Evaluating the Applicability and Sustainability of Lean Six Sigma Continuous Process Improvement Methodology to Improve Health Care Quality

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Dissertation Abstract

The health care industry has been using LSS for nearly two decades and evidence on effectiveness has been accumulating in the form of published peer reviewed journal articles. Although there have been reports of breakthrough improvements across a diverse set of industries, LSS is still considered a foreign quality improvement approach in health care and there is a lack of a comprehensive study on the applicability and effectiveness of the continuous process improvement approach as a robust enterprise QI solution.

This dissertation is presented in a 3 manuscript format and aims to provide a comprehensive study of how LSS has been used in health care, as well as a deeper analysis of whether the evidence that has been published in biomedical journals provides enough proof of its effectiveness. It also seeks to identify barriers preventing sustainable results in an effort to uncover factors that may provide information to health care professionals on whether to adopt this methodology.

Chapter 2, a systematic literature review is presented that investigates LSS articles that have been published in biomedical journals and provide examples of where this QI methodology has been successfully used. In Chapter 3, an evaluation of the quality of the LSS articles that have been published in peer reviewed journals is presented to understand whether health care professionals are able to use these reported results as evidence of LSS effectiveness in health care. In Chapter 4, an analysis to uncover key barriers to LSS project sustainability in health care is presented followed by recommendations on how to overcome them. Lastly, in Chapter 5, a conclusion to the dissertation is presented with a summary of the key findings from the thesis articles and provide an approach to help LSS programs in health care maximize their potential through an enterprise change acceleration methodology.

In conclusion, the research found that LSS in healthcare lacks quality evidence to prove its effectiveness in providing benefits in this environment.

The advisors who provided review are: William Brieger, DrPH (Chair), Laura Morlock, PhD (Advisor), Sydney Dy, MD (Reader), Lilly Engineer, DrPH, MD, MHA (Reader), and Michael Rosen, PhD (Reader).

Table of Contents

List of Figures and Tables

List of Figures

List of Tables

1. Chapter 1: Dissertation Introduction: Determining Effectiveness and Applicability of Lean Six Sigma in Healthcare

The challenge to improve the quality and safety of patient care while simultaneously working to reduce and control the rising cost of care is shared by health care systems around the world (1). The health care industry has utilized many novel approaches to transform health care operations in efforts to address quality, safety, and cost issues: for example, implementation of quality and safety programs like the Comprehensive Unit-based Safety Program (CUSP) and TeamSTEPPS (2) (3), and enterprise resource management (ERP) tools such as SAP and Oracle to help manage and reduce resource costs (4). These safety programs and enterprise business solutions have been applied in specific departments and functions within a health system and have been successful in improving patient quality and safety as well as controlling costs. However, Lean Six Sigma (LSS) continuous process improvement methodology, which was adopted from the manufacturing industry about a quarter century ago, has been used as an enterprise approach to improve nearly all aspects of a health care operation.

LSS which combines two separate problem solving approaches – Lean Manufacturing and Six Sigma – is a systematic approach to problem solving that has been embraced by the health care industry to improve quality of care, patient safety, and reduce overall waste in the system and drive down costs (5). Essentially, LSS helps eliminate defects throughout an organization, which in healthcare can mean preventing medical errors, decreasing patient harm, reducing lengths of stay, improving patient care, and improving quality (5).

LSS is not totally a new methodology, rather Lean Thinking and Six Sigma process improvement approaches are the synthesis of a series of the century long development of quality improvement (6). Lean Thinking emerged in Japan with the Toyota Motor Company leading the way in the automobile industry after World War II (7). As a result of the Toyota Motor Company adopting Lean Thinking to remove waste in the system and improve efficiency and quality, Toyota is now regarded as a leader in producing quality products (8). Similarly, the Six Sigma process improvement methodology was born in the manufacturing field and originally introduced by Motorola in the 1980s to improve product quality, but was deployed as an enterprise quality culture movement by General Electric in the mid-1990s. Lean Thinking and Six Sigma have gone through parallel developments over the course of the last half-century and provide proven tools and techniques to solve difficult business challenges (8) (9) (10).

Lean Thinking

Lean, as it is often called, represents an integrated system of principles, tools, practices, and techniques focused on developing a “lean” organization that consistently meets customer demands by synchronizing workflows, reducing waste, and managing resources to optimize efficiency and improve cycle times (11) (12) (13). Lean embraces a continuous improvement strategy that supports more visual forms of problem identification and creating simple and direct pathways and eliminating rework and bottlenecks in the system. Lean Thinking is thus less dependent on a prescriptive methodology but follows a set of five guiding principles of how processes should be designed and maintained.

Authors Womack and Jones describe these Lean principles as (14):

- Specify what creates ***value from the customers' perspective*** and drive improvement outcomes to deliver greater value for the customers
- Identify all steps across the entire ***value stream***
- Make those actions that ***create value for the customer flow efficiently***
- Only make what is ***pulled by the customer***, just in time
- ***Strive for perfection*** by continually removing successive layers of waste

A lean organization follows these principles and all employees are empowered to identify and remove waste to improve flow and efficiency.

Lean's strength lies in its set of relatively simple standard solutions to common challenges (7). Due to the simplicity of conducting Lean projects, most lean projects do not require a complex team structure and can be executed relatively quickly. Some argue that since Lean lacks a comprehensive root cause analysis in its approach, Lean is limited to producing quick fixes and is not suitable for bigger and complex issues that require precise solutions. Additionally, since Lean doesn't incorporate a monitoring and evaluation process, it is difficult to control and sustain the improved process (12). Many view these criticisms as fair, especially in health care where every procedure should be evidence based--a criterion which requires a much more robust and standardized way of reporting improvement results, including both how Lean was used and how it reduced inefficiencies.

Six Sigma

Six Sigma is a structured data-driven process improvement methodology with robust emphasis on delivering high quality products and services consistently by developing solutions to key enterprise challenges based on quantitative data analysis. There are three key elements of quality that Six Sigma programs focuses on to delight the customer:

1. The customer – identify the customer's critical to quality (CTQ) requirements through active voice of the customer (VOC) inputs, and deliver products and services that exceeds those CTQs
2. The process – identify areas to add significant value or improvement from the customer's perspective by understanding the transaction lifecycle from their needs and processes
3. The employee – provide opportunities and incentives for employees to focus their talents and energies on continuously looking for ways to improving process and creating value for the customers

By applying these elements and utilizing a prescriptive five-step problem solving methodology (6): Define, Measure, Analyze, Improve, and Control (DMAIC) (*Table 1*) – Six Sigma projects aim to deliver quality by ultimately reducing defects and variation in processes.

Table 1: Six Sigma DMAIC methodology

Description of the Six Sigma DMAIC Methodology
1. **Define** the problem statement and clarify scope and measureable goals
2. **Measure** the as-is performance of the process and identify performance gaps
3. **Analyze** the data and identify root cause of defects and waste
4. **Improve** the process with innovation and leading practices aimed at eliminating root causes
5. **Control** the improved state by implementing error proofing measures and monitoring performance

This approach is similar to that of good medical practice used since the time of Hippocrates – relevant information is assembled followed by careful diagnosis, then treatment is proposed and implemented, followed by monitoring and evaluation to see if the treatments are effective. Although the data driven approach of Six Sigma creates the most evidence based solutions of the two QI approaches; Six Sigma's limitation lies in its robust methodology (15). Some argue that many process challenges can be improved with simple common solutions and do not require the robust data-driven DMAIC methodology (12).

Lean Six Sigma (LSS)

LSS was developed in the early 2000's by Six Sigma practitioners to take advantage of the strengths of both approaches: the robust process improvement DMAIC methodology from Six Sigma and simple and quick fixes offered by Lean Thinking. Through capturing the benefits of both approaches, LSS consists of principles, tools, and techniques that provide a more robust approach to process improvement and allow QI practitioners greater flexibility in addressing many different process challenges (12). LSS utilized in health care leverages the customer focused QI approach to improve services and processes such as:

- Patient access
- Evidence based care provisions
- Patient safety
- Patient experience
- Patient engagement
- Care coordination

As LSS programs follow the Six Sigma program structure, the training for LSS is provided through the same “belt based” training system similar to that of Six Sigma. The belt personnel are labeled as green belts, black belts, and master black belts, which designate the level of LSS proficiency and experience of the certified individuals (*Table 2*).

Table 2: LSS certification level taxonomy

Certification Level	Minimum Years of Experience	Capability Description
Green Belt	2-3	A part time role and normally commits 10% of their work week to LSS projects. Lead smaller scoped projects with the assistance of a Black Belt project mentor.
Black Belt	3-8	Normally a full time position. Lead larger scoped projects and mentor Green Belts on these projects. Also provide Green Belt training.
Master Black Belt	8+	Full time role who serves as a LSS program director, trainer, operations strategist, and also lead complex enterprise level projects.

One challenge to utilizing LSS is that it requires an organization to commit significant investment in resources to the staffing and training of process improvement teams. The costs associated with deploying LSS can include consultant fees, training, books, Minitab statistical software, and costs associated with employees’ time away on training and working on quality improvement activities (16). GE reported in its 2002 Investor Relations Annual Report that it had invested approximately $15 billion or 0.4% of its revenues between 1996 and 1999

(16; 17) to their Six Sigma program. Though GE's investment example seems large, many organizations have spent significant portions of their revenue to implement LSS as well. To justify investments in LSS, organizations have traditionally set minimum project cost savings targets to be that of about four times return on a Black Belt's time and cost to train; which equals to be about $300,000 per project with a two project per year goal (18). Indeed, this high cost of implementing a LSS program highlights the difficult decision an organization's leadership must make to determine whether to train and equip their employees to conduct Lean Six Sigma projects or use lesser robust QI methods.

2. Chapter 2: A Systematic Review of Original Lean Six Sigma Process Improvement Projects in Health Care

2.1 Abstract

Background: Health care systems require constant innovation and improvement to not only advance health care quality but also to improve operations and drive down costs in order to stay competitive. Six Sigma (SS) and Lean Six Sigma (LSS) process improvement methodologies have been adopted from outside of the health care industry and used by many hospitals globally to address clinical and operational challenges and provide higher quality health care with better value. The authors conducted a systematic review of original process improvement projects using SS/LSS that were conducted across a wide spectrum of health care disciplines and functions to assess applicability and efficacy of these methodologies for the health care industry.

Methods: The following databases were searched for articles with search date ranging from 1990 to 2013: Embase, PubMed, the Cochrane Database of Systematic Reviews, and ProQuest. Articles were also found by searching the reference lists of the articles identified and including those that met the inclusion criteria and also searching on Google using our search terms. The date last searched was January 10, 2014.

Results: The authors identified 985 articles on SS and LSS, however only 44 of these articles met the strict requirements to be considered original SS/LSS peer reviewed projects conducted in a health care setting. The aims of the 44 projects that were reviewed included cycle time reduction (18), defects reduction (14), quality improvement (10), and cost reduction (2) across diverse health care disciplines including Surgery, Pharmacy, Critical Care, Labs, and Internal Medicine. Only four out of 44 articles compared their improvement outcomes with a control group design; however, a little more than half (23 articles) provided statistical analyses comparing pre and post intervention outcomes.

Conclusion: This systematic review demonstrated that most SS/LSS projects published in academic venues showed positive effects in improving processes within a wide spectrum of health care disciplines and functions. However, the quality of these articles is suboptimal in demonstrating the evidence of the projects' outcomes and their implications. Improving the quality of these articles reporting quality improvement projects using SS/LSS will help health care organizations in both conducting their projects and sharing the information, thus building a greater evidence base on the application of SS/LSS methodologies in health care.

2.2 Introduction

Health care performance, quality, and value have captured the worldwide attention of policymakers, health care system administrators, and academics (1). The reason for this high interest is in part due to high visibility health care issues such as rising costs, aging populations, health market failures, poor quality and variations in practice, medical errors and injuries, and lack of accountability (1). These challenges that affect health care systems worldwide have created widespread perceptions of unsatisfactory quality and poor value for money spent (1). Furthermore, health care spending as a percentage of Gross Domestic Product (GDP) has increased across all industrialized countries in the past twelve years which may suggest that more effort has been made to improve health care; however, the highest spending countries are not always providing the best results (19).

The U.S. health system is the most expensive system in the world with annual increases in health care costs historically outpacing overall inflation rates (20). According to the American Health Insurance Plan (AHIP), more than one-sixth of the U.S. economy is spent on health care and that percentage continues to rise every year (21). The higher costs of U.S. health care don’t necessarily mean it is any better than health care in other countries as comparative analyses for many years consistently show the U.S. underperforms relative to other Organization for Economic Co-operation and Development (OECD) countries on most performance dimensions (22). In fact, according to a recent study by the Commonwealth Fund in 2010, compared with six other nations—Australia, New Zealand, the United

Kingdom, Germany, the Netherlands, and Canada —the U.S. health care system ranked nearly last or last on five dimensions of a high performance health system: quality, access, efficiency, equity, and healthy lives (22). Regrettably, the U.S. health system is spending more on health care than any other country, and the value is not commensurate with the estimated $2.7 trillion spent annually on health care (21). Experts agree that nearly 30 percent of that spending – up to $800 billion a year in the U.S. – goes to care that is wasteful, redundant, or inefficient (21).

Many hold the view that there is room for improvement in most health care systems, and that ‘business as usual’ is no longer acceptable (23). In addition, it is becoming clearer that improvements have to come from both within and beyond the traditional health care system boundaries (23). Health systems around the world have taken notice as well and are increasing systematic efforts to innovate and improve health care quality and patient safety, reduce waste and cost, and improve access. As Wachter stressed in his book "Understanding Patient Safety," our health care system requires assessment from translocational perspectives outside of the health care sector and needs to actively apply methodologies from other fields to improve quality and safety (24). As such, health systems globally have been looking for innovative ways to improve quality and reduce costs from outside of the health care industry. The Six Sigma (SS) and Lean Six Sigma (LSS) process improvement methodologies, initially developed to improve manufacturing processes, have been utilized globally to improve quality and reduce costs across nearly every industry (25). In fact, many of the top Six Sigma companies including GE, Motorola, Ford, and Honeywell have reported cost savings between 1.2% to

4.5% of their yearly revenues from Six Sigma activities (17). If we apply these savings estimates from the industry to the $2.7 trillion healthcare market, there is an opportunity to save anywhere from $3.2 billion to $121 billion annually by implementing Six Sigma in health care.

With SS/LSS's proven effectiveness in many industries, they have been actively applied to health care settings and have been one of the most highlighted examples of such translocational application of quality improvement approaches in the field of health care.

Two process improvement approaches from the manufacturing industry – Lean and SS – initially gained popularity in the health care field (26). SS was developed by Motorola in the early 1980s by Motorola engineers who decided that the traditional quality measurement approaches of measuring defects in thousands of opportunities didn't provide enough granularity and resulted in unacceptable low quality. Instead, they developed the standard of measuring defects per million opportunities (DPMO) and the methodology to improve processes by striving for six sigma quality which is attained by achieving only 3.4 DPMO (27). Since then, hundreds of companies around the world have adopted SS as a way of doing business. The SS quality improvement methodology follows a prescriptive five-step approach called DMAIC (Define, Measure, Analyze, Improve, and Control) to improve existing processes. It utilizes statistical hypothesis testing to identify root causes that create defects in existing processes, and then develops data driven solutions.

Lean Thinking is another quality improvement approach developed in the 1940s by Toyota Motor Company that is a principles-based approach that aims to visually identify and eliminate waste in the system and improve process times as its core objective (28). Authors James P. Womack and Daniel T. Jones published a landmark book in 1996 called Lean Thinking that has been used as a key reference to five Lean principles, which include (14):

- Specify the value desired by the customer
- Identify the value stream for each product or service providing that value and challenge all of the wasted steps
- Make the product or service flow continuously through the remaining value-added steps
- Introduce pull between all steps where continuous flow is possible
- Manage toward perfection so that the number of steps and the amount of time and information needed to serve the customer continually falls

In the early 2000s SS practitioners added Lean tools and best practices to the DMAIC methodology to create LSS and in 2002 authors Michael George and Robert Lawrence published the LSS concepts in a book titled Lean Six Sigma: Combining Six Sigma with Lean Speed (9). The key difference between Lean and SS/LSS is that SS/LSS relies on data driven approaches to identify root causes while Lean identifies problems/issues using visual and less data driven methods. The two process improvement approaches, Lean and SS/LSS, both aim to improve quality and patient safety and reduce costs by eliminating waste and standardizing improved processes; however since Lean projects are conducted generally in an ad hoc just-in-time fashion and SS/LSS projects require a structured methodology and project teams, project execution vastly differs between the two. In this study, we chose to assess the efficacy of the structured SS/LSS approach for use in health care by conducting a comprehensive literature review. From the literature review, we hope to identify where in health care SS/LSS approaches are being used effectively to improve quality and patient safety and reduce costs.

2.3 Methods

A systematic review was performed with reference to current best practice. This review was conducted in close adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement 14 (29). Detailed methods are as follows:

Eligibility criteria

All published studies from peer-reviewed journals that met the inclusion criteria (see below) were included initially. We restricted peer-reviewed articles to be in English only but did not restrict country of origin.

Information sources

The following databases were searched for articles with search date ranging from 1990 to 2013: Embase, PubMed, the Cochrane Database of Systematic Reviews, ProQuest. Articles were also found by examining the reference lists of the articles identified and included in the review if they met the inclusion criteria. We also searched for articles on Google using our search terms. The date last searched was January 10, 2014.

Search

Search terms were devised to cover the health care field and the names and synonyms of the SS/LSS quality improvement (QI) methodologies. They included each of the following terms: ‘‘Six Sigma*’’, ‘‘Lean Six Sigma*’’, ‘‘Lean*’’, combined with the Boolean operator ‘AND’ with each of the following terms: ‘‘process* improvement’’, ‘‘toyota production system’’, ‘‘6 sigma’’, ‘‘lean process*’’, ‘‘lean thinking’’, ‘‘lean sigma’’ in the title or abstract.

Study selection

The criteria for article inclusion were: article was published in a peer-reviewed journal; article described a study involving hospital based health care quality improvement; article described LSS or SS methodology (the intervention; see above); and the article described the conduct of an original study. Studies were excluded if the article was a conference abstract, editorial, letter, opinion, audit or review; the population studied was non-health care based; or the article did not provide outcome data.

Three reviewers decided initial eligibility based upon the abstracts of the articles. If an abstract was not available or did not provide enough information regarding inclusion criteria, the full-text reference was accessed. Each of the three reviewers made one’s own decision based on the criteria, and if there were disagreements, they were resolved by achieving consensus among all three reviewers over videoconference.

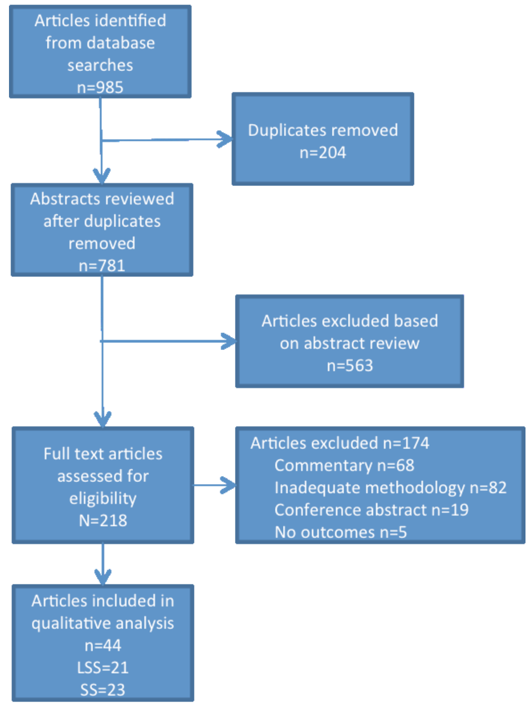
Data collection process and data fields

Data from article abstracts were collected and tabulated independently by two reviewers on to a data extraction sheet (Microsoft Excel 2010; Microsoft Corporation, Redmond, Washington, USA), guided by the Cochrane Handbook Part 2 that provided instruction on defining the study questions, developing criteria for including studies, planning the search process, and designing data collection forms and collecting the data (30). Data collected included first author, country where project was conducted, year of publication, hospital environment (e.g., academic tertiary care center, community hospital, private hospital), medical department (e.g., surgery, internal medicine, emergency department), project focus area (e.g., intensive care unit, medication use, automated lab), improvement category (e.g., cycle time reduction, defect reduction, quality improvement), whether the QI scope was a repeatable process, statistical significance of the outcomes presented, interventions and outcomes, and whether the quality improvement (QI) methodology used was SS or LSS.

2.4 Results

Study selection

Figure 1: Article selection approach



Search of the databases yielded 985 citations. An initial review of the citation titles resulted in the removal of 204 duplicate articles. After reviewing the abstracts, 563 were discarded, as they did not meet the inclusion criteria. The full text of the remaining 218 articles was examined in more detail. Sixty-eight commentary articles were removed because these were not original project reports. Eighty-two articles were rejected because these articles either just reported using SS/LSS tools but without the methodology, or reported using only certain phases of the SS/LSS methodology. Additionally, we rejected 19 conference abstracts and five articles that did not provide any outcomes. After applying our study selection methods, only 44 articles met the inclusion criteria and were included in the review (*Figure 1*).

Our data search found 21 articles that used LSS and 23 articles that utilized SS. The earliest article that met our search criteria was published in 2004 and 2010 had the most articles published with 11 out of the 44. The majority of the studies (N=28) were conducted in an academic tertiary care center environment, followed by 6 articles with projects conducted in a multi-hospital setting.

There was a diverse mix of projects conducted in several core hospital departments: Surgery had the most projects with 11 published articles, followed by Internal Medicine with 7 and Nursing and Pharmacy with 5 published articles each. The aims of the 44 projects included cycle time reduction (18), defects reduction (14), quality improvement (10), and cost reduction (2) (*Table 3*). A little more than half (N=23) provided a statistical test for the significance of improvement with a pre and post intervention design (*Table 4*).

Table 3: SS and LSS project distribution categorized by Medical Department, Hospital Environment, and Aims of the Study

	SS		LSS		Total	
Category	**n**	**%**	**n**	**%**	**n**	**%**
Functional Department						
Surgery	6	14%	5	11%	11	25%
Internal Medicine	4	9%	3	7%	7	16%
Nursing	2	5%	3	7%	5	11%
Pharmacy	3	7%	2	5%	5	11%
Radiology	2	5%	2	5%	4	9%
Pathology	3	7%	1	2%	4	9%
Emergency Department	1	2%	1	2%	2	5%
Public Health	0	0%	2	5%	2	5%
Behavioral Health	1	2%	0	0%	1	2%
Medical Education	0	0%	1	2%	1	2%
Patient Transport	1	2%	0	0%	1	2%
Primary Care	0	0%	1	2%	1	2%
Total	***23***	***52%***	***21***	***48%***	***44***	***100%***
Health Care Environment						
Academic Tertiary Care Center	13	30%	15	34%	28	64%
Multihospital Health System	5	11%	1	2%	6	14%
Community Hospital	1	2%	3	7%	4	9%
Private Hospital	2	5%	1	2%	3	7%
Ancillary Service Provider	1	2%	0	0%	1	2%
Commercial Health Plan	1	2%	0	0%	1	2%
Veterans Affairs	0	0%	1	2%	1	2%
Total	***23***	***52%***	***21***	***48%***	***44***	***100%***
Aims of the Study						
Cycle Time Reduction	7	16%	11	25%	18	41%
Defect Reduction	10	23%	4	9%	14	32%
Quality Improvement	5	11%	5	11%	10	23%
Cost Reduction	1	2%	1	2%	2	5%
Total	***23***	***52%***	***21***	***48%***	***44***	***100%***

Table 4: Assessing LSS and SS projects in health care

Reference	Country	Year	Health Care Environment	Department	Focus Area	Aims of the Study	Tests of Statistical Significance	Outcomes	QI Methodology
Taner, M et al. (26)	Turkey	2011	Private hospital	Radiology	Diagnostic imaging	Cycle Time Reduction	N	Repeat imaging sessions and delays were addressed through training and education to physician, radiologists and radiology technicians. Improvement outcomes were measured in Sigma levels for 4 months. Sigma level improved from 3.5 to 4.2 in 4 months. Additionally training of staff resulted in volume increase of 9.5% and decrease in repeat examinations by 84.12%.	SS
Kelly, E et al. (27)	USA	2010	Academic Tertiary Care Center	Emergency Department	Myocardial infarction/ door to balloon	Cycle Time Reduction	Y P<.001	Mean door to balloon times reduced from 128 min to 56 min with 100% of pts. Meeting the 90 min target for the year 2010. Key improvements were to develop a (ST segment elevation myocardial infarction) STEMI treatment protocol.	SS
Gayed, B et al. (28)	USA	2013	Veterans Affairs	Surgery	Perioperative	Cycle Time Reduction	Y P<.001	Length of Stay (LOS) decreased 36% overall, decreasing from 5.3 days during the pre-project period to 3.4 days during the 20 month sustainment period with a P Value <0.001. Non-VA care was completely eliminated for patients undergoing total hip and knee replacement producing an estimated return on investment of $1 million annually when compared with baseline cost and volumes.	LSS
Toledo, A et al. (29)	USA	2013	Academic Tertiary Care Center	Surgery	ICU	Cycle Time Reduction	Y P<.018	Median LOS decreased significantly from 11 days before the intervention to 8 days post intervention and was maintained for 24 months after the study (P Value<.018). Readmission rates showed no statistical significance (P Value = .63). By reducing LOS without compromising readmission rates, this project has yielded vast financial benefits for the institution.	SS
Niemeijer, G et al. (30)	Netherlands	2012	Academic Tertiary Care Center	Surgery	ICU	Cycle Time Reduction	Y P=0.000	Significant improvements in both overall mean LOS and duration of surgery (P=0.000), with decreases of 13.5 days to 9.3 days and 154 minutes to 98 minutes, respectively after the implementation of the clinical pathways. The financial reward of the LOS reduction was an annual cost savings of €120 000.	LSS
Lin, S et al. (31)	USA	2013	Academic Tertiary Care Center	Surgery	Perioperative	Cycle Time Reduction	Y P=.042	Patient lead time from clinic arrival to exam start time decreased by 12.2% on average with P-value = .042. On time starts for patient exams improved by 34% (P<.001) while excess patient motion was reduced by 74 feet per patient, which represents a 34% reduction in motion per visit.	LSS

Fairbanks, C et al. (32)	USA	2007	Community hospital	Surgery	Perioperative	Cycle Time Reduction	N	Wait times before surgical procedures improved 2.4% from 85.7 to 88.1. Patient survey satisfaction scores improved during the quarter following the implementation of solutions.	LSS
Bush, S et al. (33)	USA	2007	Academic Tertiary Care Center	Surgery	OBGYN	Cycle Time Reduction	N	Wait times for new obstetrical visits decreased from 38 to 8 days. The patient time spent in the clinic reduced from 3.2 to 1.5 hours. Initial gynecologic visits increased by 87%, and return visits increased by 66%, repeat visits increased by 45%. Gross clinic revenue increased by 73%. Contrast the comparison group (internal medicine department remained unchanged).	SS
Cima, R et al. (34)	USA	2011	Academic Tertiary Care Center	Surgery	OR	Cycle Time Reduction	Y P<.05	Standardized room allocation guidelines, and parallel processing led to enhanced efficiency. On-time starts improved across thoracic, GYN, and GEN, as did Operations past 5 PM (P<.05). Also, average turnover time, and OR operating margin all improved.	SS
Albert, K et al. (35)	USA	2010	Community Hospital	Internal Medicine	ICU	Cycle Time Reduction	Y P<.0001	Use of standardized CHF order sets reduced Length of Stay (LOS) from 7 days to 4 days (P<.0001).	SS
Fischman, D (36)	USA	2010	Academic Tertiary Care Center	Internal Medicine	Residency	Cycle Time Reduction	Y P=.002	No significant improvement in total encounter duration was found between the intervention and control groups. However, there was significance for cycle time of end of triage and the beginning of physician encounter 5 min vs. 14 min (P=.002). “No show” data showed significance P=.049 between Nov 2008 and February 2009 and that no show rates trended down as Post graduate year increased from 1 to 3.	LSS
Deckard, G et al. (37)	USA	2010	Multihospital Health System	Primary care	Referral	Cycle Time Reduction	N	The referral process was reduced in Genitourinary (GU) from 60.5 to 37.5 days and in GYN from 135 to 34.9 days. Improvements include centralized work management process.	LSS
Capasso, V et al. (38)	USA	2012	Community Hospital	Nursing	Medication use	Cycle Time Reduction	N	The number of interruptions per med-pass dropped from 4 to 1 on average. The percentage of med-pass interrupted reduced from 93% to 50%, and time per interruption dropped from 6 min to 0.3 min, saving the staff an estimated 15,000 hours per year which is equal to gaining 7 FTEs.	LSS
Aakre, K et al. (39)	USA	2010	Academic Tertiary Care Center	Radiology	Bone densitometry	Cycle Time Reduction	N	Improvements to improve the flow resulted in a 3 minute average reduction in patient cycle time which represented a 15% reduction with no change in staff or costs.	LSS
Chand, DV (40)	USA	2010	Academic Tertiary Care Center	Medical Education	Residency	Cycle Time Reduction	Y P<.05	Collaborative, family centered rounding with elimination of the "pre-rounding" process, as well as standard work instructions and pacing the process to meet customer demand (takt time) reduced non-value added time by 64% (P<.05).	LSS

Stoiljkovic, V et al. (41)	Serbia	2011	Private hospital	Pathology	Sample processing	Cycle Time Reduction	N	Solutions have improved Day O (preparation) cycle time of 5.7 hours/day, Day 1 (1st reading) cycle time of 7.3 hours/day, and Day 2 (1st reading) cycle time of 5.2 hours/day.	LSS
D'Young, A et al. (42)	New Zealand	2013	Academic Tertiary Care Center	Public Health	Hemophilia bleed reporting	Cycle Time Reduction	Y P<.05	Outcomes on mean time to report were stratified by four groups: Age, Ethnicity, Region, and Disease Severity. Many of the stratified groups showed statistically significant improvements between pre and post improvement times (P<.05).	LSS
Silich, S, et al. (43)	USA	2011	Academic Tertiary Care Center	Patient Transport	Patient Transport	Cycle Time Reduction	N	The goal of transferring patients between ICU and critical care units (CCU) within 90 minutes was achieved from baseline of 214 minutes to 84 minutes.	SS
Eldridge, N et al. (44)	USA	2006	Academic Tertiary Care Center	Internal Medicine	ICU	Defects Reduction	Y P<.001	Observed compliance increased from 47% to 80%, based on over 4000 total observations (P<.001). The mass of ABHR used per 100 patient days in 3 ICUs increased by 97%, 94%, and 70% and increases were sustained for 9 months.	SS
Carboneau, C et al. (45)	USA	2010	Academic Tertiary Care Center	Internal Medicine	ICU	Defects Reduction	N	Improved hand hygiene compliance from 65% to 82% by implementing a variety of improvements based around developing staff and patient education, culture and awareness, and environment. An estimated number of lives saved was 2.5 lives and overall prevention of 41 MRSA infection resulted in a gross savings of $354K.	LSS
Frankel, H et al. (46)	USA	2005	Academic Tertiary Care Center	Surgery	SICU	Defects Reduction	Y P<.0001	Interventions had a significant impact to catheter related bloodstream infections (CR-BSI), reducing it 650% from 11 to 1.7 per 1000 catheter days (P<.0001). Additionally, the adoption of chlorhexidine-sliver catheters in high risk patients had a considerable impact in reducing CR-BSI (50% reduction: P<.05).	SS
Cima, R et al. (47)	USA	2013	Academic Tertiary Care Center	Surgery	OR	Defect Reduction	Y P<.05	Their baseline surgical site infection (SSI) rate between 2009 and 2010 was 9.8%. One year after implementation of the SSI reduction bundle, they demonstrated a significant reduction (P<.05) in both overall and superficial SSIs, to 4.0% and 1.5% respectively.	LSS
Drenckpohl, D et al. (48)	USA	2007	Academic Tertiary Care Center	Internal Medicine	NICU	Defects Reduction	N	Between Dec 2003 and March 2006, the NICU has had no documented cases of misappropriated breast milk. An appropriate and effective breast milk admin policy developed by identifying potential errors and developing mitigating steps lead to reduced misappropriation of EBM.	SS
Veluswamy, R et al. (49)	USA	2010	Community Hospital	Nursing	ICU	Defects Reduction	N	Decreased falls from 8.7:1000 to 2.2:1000 a 295% improvement by implementing solutions such as bedside commodes, hourly rounds, nursing assistants,	LSS

								PT evaluations, medication screening, alarm systems, and stakeholder education.	
Esimai, G (50)	USA	2005	Academic Tertiary Care Center	Pharmacy	Medication use	Defects Reduction	N	Reduction of error dropped from 213 in Feb to 96 in June, a 55% reduction by implementing education, Decrease in total error rate from .33% to .14% in five months. Estimated labor cost savings of $550K annualized at $1.32 M).	LSS
Castle, L et al. (51)	USA	2005	Ancillary Service Provider	Pharmacy	Medication use	Defects Reduction	N	Implemented SOPs for sound alike/look alike (SALA) alerts and system enhancements to improve processing consistency that reduced wrong drug selection by 33%, wrong directions by 49%, SALA errors by 69%.	SS
Kapur, A et al. (52)	USA	2012	Multihospital Health System	Radiology	Nuclear medicine	Defects Reduction	N	Number of computed potential no-fly delays per month dropped from 60 to 20 over a total of 520 cases. The fraction of computed potential no fly cases that were delayed in no-fly potential compliance rose from 28% to 45%. For potential no fly cases, event reporting rose from 18% to 50%, while for actually delayed cases, event reporting rose from 65% to 100%.	SS
Egan, S et al. (53)	Ireland	2012	Academic Tertiary Care Center	Pharmacy	Medication use	Defects Reduction	Y P<.0001	The attainment of serum level sampling in the required time window improved by 85% (P<.0001). A 66% improvement in accuracy of dosing was observed (P<.0001)	SS
Chan, A (54)	Taiwan	2004	Private Hospital	Pharmacy	Medication use	Defects Reduction	N	Reduced dispensing errors from 338.8 to 230 errors per million post intervention.	SS
Neri, R et al. (55)	USA	2008	Multihospital Health System	Pathology	Transfusion	Defects Reduction	N	Reduced inappropriate transfusions of packed RBC from 16% to 5%, improved clinician use of a blood component order form, establishment of internal benchmarks, enhanced lab to clinician communication, and better blood product expense control. Saved $121K in 2005.	SS
Leaphart, C et al. (56)	USA	2012	Academic Tertiary Care Center	Surgery	Transplants	Defects Reduction	Y P<.0001	Aggressive goal to reduce abnormal serum sodium levels from a baseline of 92.6% to <10% (P<.0001) was achieved. Now abnormal serum sodium levels at 7.8% by identifying root cause root cause and creating policy change to administer .9% sodium chloride during renal transplantation.	SS
Riebling, N et al. (57)	USA	2005	Multihospital Health System	Pathology	Automated lab	Defects Reduction	N	Improved staff training, simplified results review guidelines were provided to technologists as an aid in the critical decision making process used to validate test results. Also the auto verification process was modified to capture real time suspect flags for CBC orders. These improvements improved sigma level from 4.8 to 5.0 and improved volume as well.	SS

Parker, B et al. (58)	USA	2006	Academic Tertiary Care Center	Surgery	Anesthesiology	Quality	Y P<.01	The percentage of patients receiving antimicrobial prophylaxis within 60 min of incision improved from a baseline of 38% for 615 surveyed surgical procedures to 86% for 1716 surveyed post intervention P<.01.	SS
Martinez, E et al. (59)	USA	2011	Academic Tertiary Care Center	Internal Medicine	ICU	Quality	Y P<.001	At the completion of the interventions, the average number of glucose measurements/patient/day increased significantly over the study period from 3(±4) at baseline and phase 1 to 12(±4) during the final phase (P<.001).	LSS
Yamamoto, J et al. (60)	USA	2010	Academic Tertiary Care Center	Radiology	Medicine administration	Quality	N	Reduced the proportion of patients with low blood glucose levels within range, from 1.1% to .8% of patients experiencing low blood glucose levels (<50 mg/dL). 98% of meals delivered on time.100% of inpatients have radiology services scheduled within acceptable times for radiology testing.	LSS
Yamamoto, J et al. (61)	USA	2010	Academic Tertiary Care Center	Pharmacy	Medication use	Quality	Y Outcome 1: P=.0008 Outcome 2: P=.0155	Significantly few patients experienced blood glucose levels over 180 mg/dL, 23.2% compared to 20.4% (P=.0008). Additionally, compared to pre LSS, significantly fewer patients experienced blood glucose levels less than 50 mg/dL (1.1% vs. .8%, P=.0155). Improvements resulted in efficiency and cost savings of $75K.	LSS
Calhoun, B et al. (62)	USA	2011	Academic Tertiary Care Center	Pathology	Automated lab	Quality	Y P<.001	By standardizing and automating workflow utilizing automated workflow tool called Soarian, they improved on the number of Pap smears outside of the 7 day window from 5.3% in 2008 to 2.6% in 2009 (P<.001).	SS
Elberfeld, A et al. (63)	USA	2004	Multihospital Health System	Nursing	Medication use	Quality	N	Improvements made through the project delivered targeted results meeting all CMS indicators.	SS
Neufeld, N et al. (64)	USA	2013	Academic Tertiary Care Center	Nursing	Discharge planning	Quality	Y P<.001	Improved compliance of discharge paperwork completeness from 61.8% to 94.2% (P<.001). The percentage of charts that were 100% complete increased from 11.9% to 67.8% (P<.001).	LSS
DuPree, E et al. (65)	USA	2009	Academic Tertiary Care Center	Internal Medicine	Pain Management	Quality	N	Improved Overall Patient Satisfaction with pain management "Excellent" ratings from 37% to 54%, and both the medicine and surgery units surpassed their goal of at least 50% of responses being in the “excellent” category.	SS
Beard, G (66)	USA	2008	Commercial Health Plan	Behavioral Health	Clinical Intervention Program	Quality	Y P=.000	Interventions improved clinical outreach to members from a baseline of 7% to 20% post intervention (P=.000).	SS
Hina-Syeda, H et al. (67)	USA	2013	Academic Tertiary Care Center	Public Health	Immunization	Quality	N	Project improvements resulted in improvements to their immunization compliance from a baseline Z score of 1.96 and a yield of only 67.7% to post intervention Z score of 3.9 with a yield of 93.5%, respectively.	LSS

Elberfeld, A et al. (68)	USA	2007	Multihospital Health System	Nursing	Revenue cycle	Cost Reduction	Y P=.042	The interventions improved the HHRG case-weight mix from 1.07 to 1.26 (P=.042). A financial gain of $1.2 M for the first year was directly linked to the improvements.	SS
Pocha, C et al. (69)	USA	2010	Academic Tertiary Care Center	Emergency Department	ER	Cost Reduction	N	Interventions have reduced unnecessary chest x-rays in the ED by 9% from baseline. Depending on ED volume, their interventions would save the ED between $5,974 to $10,303K per year.	LSS

Descriptive synthesis of results

There was great diversity in the application of SS/LSS across the hospital environment, from the settings and aims to interventions. The sections below, which are organized by improvement category, describe the focus areas of process improvement, the interventions, and the contribution of the project to improving health care performance.

Reducing delays/ cycle time reduction

Reducing delays and cycle times in medical care processes was a major focus of the articles that were assessed. Over 42% (N=18) of the articles included in the review were in this category; the projects spanned many subspecialty areas.

<u>Reducing delays / cycle time in Radiology/Imaging</u>

One project was identified with the objective of reducing imaging cycle times. Taner, M and team in 2011 conducted a project that improved diagnostic imaging workflow by using SS methodology and tools such as process maps, Failure Mode and Effects Analysis (FMEA) to identify six failure modes that caused repeat imaging sessions and delays. FMEA is a qualitative analysis tool used to systematically identify potential failure modes in the process and determine the risk to the system by grading the failure modes in terms of severity, occurrence, and level of detection (9). The team identified that the root causes of these issues were related to the malfunction of the radiology information system and picture archiving and communication system (RIS/PACS) and improper positioning of patients. The interventions included implementing RIS/PACS functionality training to physicians on how to effectively use the electronic system, and to radiologists and technologists on equipment calibration and maintenance, patient care and positioning, and film reading. Although tests of statistical significance were not performed, the authors reported improvement outcomes in Sigma levels terminology where higher levels of sigma indicate a lower rate of errors. The corrective actions implemented resulted in a volume increase of 9.5% and decrease in repeat examinations by 84.2%. These outcomes represented a process quality sigma level improvement from 3.5 to 4.2 in 4 months (31). Sigma level, also known as the Z score, is a measure of quality used by SS practitioners that is measured in Defects per Million Opportunities (DPMO), where a higher sigma level represents a lower DPMO. A process that is operating at a 6 sigma level is considered to only create 3.4 DPMO, while a process that is at a 4 sigma level is creating 6,210 DPMO (10).

Reducing delays / cycle time in the Emergency Department (ED)

One article reported a SS project that reduced the “door to balloon” cycle time in the ED – the period which starts with the patient’s arrival in the ED and ends when a catheter guidewire crosses the culprit lesion in the cardiac catheterization lab (CCL). Kelly et al. published an article in 2010 demonstrating the use of SS to reduce “door to balloon” cycle time. The project team mapped the “door to balloon” process and identified inefficiencies, redundancies, or issues within each step and systematically removed unnecessary or “non-value added” activities – where “non-valued added” activities are actions in the process that do not improve the form or function of the door to balloon process in terms of quality, safety, and patient outcomes (75). Additional interventions included empowering ED attendings to activate the CCL, designation of triage “cardiac nurses” and triage beds to obtain electrocardiograms, establishment of ST segment elevation myocardial infarction (STEMI) treatment protocol for the ED and CCL, ED attending making a single call to central page operator when STEMI identified, requiring CCL staff to arrive in the CCL within 20 minutes of being paged, and requiring cardiology fellows to be within 10 minutes drive or in-house when on call. The interventions from this project resulted in significantly improving “door to balloon” cycle time from 128 minutes to 56 minutes ($P<0.001$) with 100% of patients meeting the 90 minute target for the year 2010 (32).

Reducing delays / cycle time in the Department of Surgery

Seven projects were identified that reduced cycle times in the surgery department. Three projects were identified to reduce post-surgery Length of Stay (LOS). Gayed, B et al. conducted a LSS project to reduce the LOS for the Veterans Affairs (VA) Joint Replacement Program patients. The project team developed a current state process map and determined that work processes for preoperative clinic, hospital admission, and post-operative care were largely disconnected from one another. The project team designed a single-piece flow process for the patient from the pre-operative stage through hospitalization. Single piece flow is a Lean principle that reduces or eliminates wastes that can be caused by batching, allowing processes to be streamlined (75). The results of their interventions had a statistically significant improvement of 36% reduction overall, decreasing LOS from 5.3 days to 3.4 days (P value <.001). The project also completely eliminated non-VA care for patients undergoing total hip and knee replacement, producing an estimated cost saving of $1 million annually (33).

Toledo and colleagues reduced LOS for liver transplant patients by conducting a SS project that identified several factors as root causes: lack of clinical pathway, medical delays (i.e. insulin teaching that is too difficult to do on day of discharge), inconsistent time for inpatient daily team rounds, delays in obtaining initial physical therapy, and delays in transferring patients out of the ICU after orders are written. The team implemented multiple improvements including clinical pathways; enhanced communication among physicians, staff, patients, and care givers; uniform time for daily rounds; and increased availability of outpatient transplant clinic appointments that resulted in a significant reduction in median LOS from 11 days before the intervention to 8 days post intervention (P value <.018) that was maintained for 24 months after the study (34).

Niemeijer et al. demonstrated an improvement in LOS for osteoporotic hip fracture patients in the elderly with a significant (P=0.000) reduction of overall mean LOS from 13.5 days to 9.3 days and duration of surgery from 154 minutes to 98 minutes, respectively (35). The LSS project team developed an efficient clinical pathway for hip fractures. The team mapped the value stream – where value stream is the series of events that take a product or service from its beginning through to the customer (9) – of the clinical pathway and identified two key areas for improvement. First, no standard procedures and protocols of multidisciplinary intake existed. Second, preoperative consult of the anesthesiologist took place at the nursing ward and after that additional diagnostic tests were performed depending on the co-morbidity, resulting in unnecessary movement of patients and personnel at the nursing ward. The team implemented several interventions that included: standardized multidisciplinary procedures for the diagnostic process at the ER within 120 minutes; standardized protocols for intake, and diagnostic tests by all multidisciplinary teams at the ER; standardized discharge planning, and standardized treatment protocols for both the medical and nursing departments (35).

Lin, S et al. and Fairbanks and colleagues both conducted LSS projects that improved perioperative process cycle times. Lin, S and colleagues improved patient flow through a tertiary otolaryngology clinic and significantly decreased patient lead time from clinic arrival to exam start time by 12.2% (P value = .042) and increased on time starts for patient exams by 34% (P<.001) (36). This team utilized a combination of regression analysis of process cycle times along with value stream analysis to identify process bottlenecks and waste. The team then systematically eliminated non-value added steps and resources and aligned staffing hours to meet high census demands. Fairbanks and colleagues improved patient throughput through the perioperative environment for elective surgeries by creating the nursing, anesthesia, and surgical assessments before surgery for the post anesthesia care unit (PACU) and improved on-time starts from 12% to 89%, although results were not tested for statistical significance (37).

Two projects used SS to improve cycle times in the surgery department. Bush and colleagues conducted a project in the OBGYN department to improve efficiency and patient access to their clinic by implementing revised resident scheduling templates, adding new clinic sessions and physician extenders, eliminating non-value add steps, and creating a new weekly obstetric patient-only clinic. Although statistical significance was not provided, the article reported that wait times for new obstetrical visits decreased from 38 to 8 days, patient time spent in the clinic reduced from 3.2 to 1.5 hours, initial gynecologic visits increased by 87%, return visits increased by 66%, and repeat visits increased by 45% while a comparison group (internal medicine department) remained unchanged during the same study period (38).

Cima, R et al. also conducted a cycle time reduction project in 2011 to improve operating room efficiency, which implemented various interventions such as standardized room allocation guidelines and parallel processing. Their interventions reduced non-operative time, redundant information collection, and increased staff engagement that has resulted in enhanced efficiency and improved on-time starts across thoracic, GYN, and general surgery ($P<.05$). Additionally, the article reported that improvements in patient wait times at the surgical admissions desk of longer than 10 minutes, and on-time arrival (within 30 minutes of scheduled report time) were both statistically significant ($P<.0001$) (39).

<u>Reducing delays / cycle time in Primary Care and Internal Medicine</u>

Three projects were identified that reduced cycle times in Primary Care and Internal Medicine departments. Albert and colleagues in 2010 conducted a SS project to reduce the LOS for congestive heart failure (CHF) patients. The team utilized the voice of the customer (VOC), process mapping, and FMEA tools to identify process failures and variation – where the VOC is a tool used to identify the customer's critical requirements, expectations, and preferences (9). The article reported that through the development of standardized CHF order sets, daily rounding questions, clinical measures for discharge, and home care and tele-health services, the team was able to significantly reduce LOS from 7 days to 4 days (P<.0001) (40).

Fischman and team applied LSS in 2010 to improve the clinical process that spans from the end of triage to the beginning of the physician encounter. The team identified poor patient-provider rapport and long wait times as key factors impacting quality of care. A multitude of interventions were implemented that included 20 minute patient encounter blocks, creation of registered nurse-medical assistant-physician teams, and enforcement of clinic on-time policy. These interventions resulted in significantly reducing the patient wait time between the end of triage to the beginning of the physician encounter from 14 to 5 minutes (P<.01); "no show" data also exhibited significant improvement (P=.049) (41).

Deckard, G et al. (2010) improved timeliness and efficiency in the referral process using LSS. The team identified incomplete referrals, inadequate staffing, and lack of access to specialty care appointment slots as key factors impacting the specialty referral process. The team implemented a centralized referral management process that resulted in an overall reduction in Genitourinary (GU) referral process time from 60.5 to 37.5 days and Gynecology (GYN) referral time from 135 to 34.9 days, albeit statistical significance was not provided (41).

Reducing delays / cycle time in Nursing Workflow

One project conducted by Capasso and colleagues in 2012 sought to improve medicine administration cycle time in the inpatient ward at a community hospital. Their project team conducted a value stream analysis and determined that nursing staff interruptions were a root cause of nursing not meeting its goal of delivering all medication within 60 minutes of prescribed time. The team implemented a visual tool that alerted all staff and clinical personnel in the area that a nurse is engaged in a medicine passing or administering (med-pass) round and that they were not to be interrupted. Although the outcomes were not tested for statistical significance, the intervention reduced the number of interruptions per med-pass from 4 to 1 on average; the percentage of med-pass interruptions decreased from 93% to 50%, and time per interruption dropped from 6 minutes to 0.3 minutes, saving the staff an estimated 15,000 hours per year which is equal to gaining 7 FTEs (43).

Reducing delays / cycle time in the Clinical Workflow

Two projects were identified that improved clinical workflow cycle times. Aakre and colleagues conducted a LSS project in 2010 at the Mayo Clinic in Rochester, Minnesota aimed at improving patient flow for a bone densitometry practice. This project used several tools such as Pareto and spaghetti diagrams and a value stream map to identify process wastes and workflow bottlenecks. A Pareto diagram displays categorical information in a bar graph and represents the values in descending order, while a spaghetti diagram is a graphical representation of the continuous flow of some entity as it goes through the process (9; 14). The team implemented systematic improvements that reduced or eliminated waste in the process that resulted in a 3 minute average reduction in patient cycle time with no change in staff or costs (44), although these outcomes were not tested for statistical significance. Additionally, Chand, DV et al. conducted a LSS project in 2010 that improved the efficiency of the resident rounding process by utilizing value stream analysis methods to identify process waste and eliminating non-value added steps such as pre-rounding, which resulted in reducing the non-value added time per patient by 64% ($P<0.05$) (45).

Reducing delays / cycle time in the Lab

One article was identified that reduced lab cycle times. Stoiljkovic, V. et al. in 2011 conducted a LSS project that examined how to improve the efficiency of the sample analysis process in the microbiology lab at a private hospital in Serbia. The project team used a variety of LSS tools including 5S, spaghetti diagram, Supplier Inputs Process Outputs Customers (SIPOC), and control charts to identify improvement areas. Their use of control charts revealed that there was large variation and rapid increases of lead time duration for certain samples. Interventions included redesigning the layout of the microbiology lab and the analysis process to reduce motion and transportation of samples. Although tests of statistical significance were not reported on the outcomes, the implemented solutions have improved Day 0 (preparation) cycle time from 35.1 to 29.4 hours/day, Day 1 (1st reading) cycle time from 25.4 to 18.1 hours/day, and Day 2 (1st reading) cycle time from 36.8 to 31.6 hours/day (46).

Improving public health program reporting cycle times

One project was identified with the objective of improving public health program reporting. D'Young et al. in 2013 conducted a LSS project that improved the speed at which bleeding episodes were reported and the mean number of monthly reported bleeding episodes by adults with haemophilia living in the Auckland region of New Zealand to the Auckland Regional Haemophilia Treatment Centre (ARHTC). The project team identified four variables associated with mean time to report, including age, ethnicity, region, and disease severity and conducted a multivariate data analysis to determine the effectiveness of the intervention. The project team implemented patient education and outreach programs, bleed reporting policy revisions, and patient champions to promote benefits of reporting. The article reported that relative to the initial baseline, the mean bleed reporting time and number of bleeds reported per month was improved significantly ($P < 0.05$) (47).

Reducing delays / cycle time in Patient Transport

One project identified improved patient transport process cycle times of transferring newly admitted critically ill patients to an intensive care unit (ICU). Silich et al. conducted a SS project in 2011 that reduced patient transfer times by utilizing fishbone diagrams – which is a qualitative brainstorming technique used to identify root causes (9), FMEA, and hypothesis testing to identify sources of process variation. The project team determined 5 critical elements that required intervention: 1) poor process flow; 2) inconsistent communication; 3) no standardized order writing process; 4) overutilization of remote cardiac monitoring;

and 5) lack of understanding of the importance of efficient patient transport by the staff. Key interventions included transforming a room used to house equipment into a patient bed, new policy training to staff provided by the ICU director, and implementing electric bed assignment notification software in the ICU/Critical Care Unit (CCU). The improvements resulted in meeting their goal of transfer time limits of 3 hours for any individual transfer and 90 minutes for the average of all transfers (48). The pre-post intervention differences, however, were not tested for statistical significance.

Defect and error reduction

Reducing defects in the medical care process was a second major focus of the articles that were assessed. Nearly a third (N=14) of the articles included in the review were in this category; the projects spanned many sub specialty areas.

<u>Defect and error reduction in Critical Care Units</u>

Six articles reported on defect reduction QI projects utilizing both SS and LSS methodologies in critical care unit settings. Eldridge et al. in 2006 and Carboneau and colleagues in 2010 each conducted QI projects using SS and LSS approaches respectively to increase hand hygiene compliance in the ICU setting. Eldridge et al. reported that their hand hygiene compliance improvement solutions included making physical improvements to walls, countertops, and supply closets; conducting hand hygiene policy and rules awareness training; capturing and reporting hand hygiene performance metrics; and promoting culture change through hand hygiene marketing activities. These interventions sustained an observed compliance increase from 47% to 80%, based on over 4000 total observations (P<.001) (49).

Carboneau and colleagues conducted a LSS project in 2010 to improve hand hygiene compliance. The authors reported improving hand hygiene compliance from 65% to 82% by implementing a variety of interventions mirroring best practices from other facilities. Their interventions were based on providing continuous hand hygiene education to staff and patients, creating a culture and awareness of hand hygiene, and developing an environment that is conducive to hand hygiene compliance. Although the project outcomes were not tested for statistical significance, Carboneau et al. reported an estimated 2.5 lives saved and overall prevention of 41 Methicillin-resistant Staphylococcus Aureus (MRSA) infections that resulted in a gross savings of $354K (50).

Frankel and colleagues in 2005 used SS to reduce incidence of catheter related bloodstream infections (CR-BSI) in the surgical intensive care unit (SICU). The SS project team used a fishbone diagram to identify factors potentially related to CR-BSI. They determined that lack of standards for: using a new catheter site versus changing a catheter over a guidewire, guidewire changes, insertion sites, and line insertion date; along with not using antibiotic-coated central lines were key root causes of CR-BSI. Interventions included a revised standard operating procedure (SOP) with a new management system to track: catheter indwelling time, who did the insertion, and at what body site. They also introduced antibiotic coated catheters (chlorhexidine-silver) for patients receiving ventilation for more than 4 days. Their interventions resulted in a 50% (P<.05) reduction in the infection rate and they also reported a sustained improvement of 650% from 11 CR-BSIs to 1.7 per 1000 catheter days ($P<0.001$) (51).

Additionally, Cima, R et al. in 2013 conducted a LSS project to reduce surgical site infections (SSIs). This team conducted a critical to quality diagramming session to determine critical elements that would mitigate SSIs and developed an intervention bundle. Cima and colleagues demonstrated a statistically significant reduction in SSIs ($P<0.05$) in colorectal surgery cases from a baseline SSI percentage between 2009 and 2010 of 9.8% to 4.0% and 1.5% for overall and superficial SSIs, respectively ($P<.05$) (52).

Drenckpohl, D et al. used the SS approach to reduce incidence of breast milk administration errors. The results of a root cause analysis identified six issues that caused administration errors: inconsistencies and variation in management processes regarding bottled breast milk; inconsistencies in educating parents about identifying, storing, and transporting expressed milk; staff errors due to multitasking requirements and an increased incidence of distractions; lack of formal and unified processes and limited space for milk storage; lack of accountability; and lack of communication between patient care units as to proper handling, storage, preparation and delivery of expressed breast milk. The project team developed a standardized system for intake, storage, preparation, distribution, and administration of expressed breast milk, and although tests for statistical significance were not conducted, Drenckpohl and colleagues reported that between December 2003 and March 2006, the neonatal intensive care unit had no documented cases of misappropriated breast milk (53). Additionally, Veluswamy and colleagues used LSS to reduce process defects that resulted in patient falls. Their project resulted in decreased falls from 8.7 falls per 1000 patients to 2.2 falls per 1000 patients which was a 75% reduction in falls by implementing solutions such as bedside commodes, hourly rounds, nursing assistants, PT evaluations, medication screening, alarm systems, and stakeholder education (54).

Defect and error reduction in Medication Administration and Use

Five projects reported decreasing defects in medication dispensing and use to improve patient safety. Esimai et al. and Castle et al. both produced projects in 2005 using LSS and SS respectively to decrease medication errors. Esimai and colleagues' LSS project focused on the medication order entry process and aimed to decrease medication administration records (MAR) delays and errors. The team identified several root causes including communication technology using fax lines, illegible hand written prescriptions by providers, distractions to pharmacy staff during order entry, non-reconciliation among nurses and pharmacist regarding the physician's order, and other common human errors causing defects. They implemented a higher performance standard through education and supervision, mandatory use of the computerized physician order (CPO) system by providers, and better communication processes. Although the outcome of these solutions were not tested for statistical significance, the article stated that the interventions decreased the total error rate from .33% to .14% in five months with an estimated labor cost savings of $550K annualized at $1.32 million (55).

Castle and colleagues used SS to reduce medication errors in its home delivery service. The team identified that drug selection errors and inconsistent SOPs across the organization were root causes that created medication errors. The SS team implemented standard operating procedures for sound alike/look alike (SALA) alerts and system enhancements to improve processing consistency, which reduced wrong drug selection by 33%, wrong directions by 49%, and SALA errors by 69% (56).

In another project, Kapur et al. in 2012 used SS to identify the root issues that led to human errors in administering nuclear medicine. They improved patient safety by implementing a quality-checklist process map (QPM) with “no-fly” (“no-fly” are patients who have not met the requirements to receive radiation treatments) process interlocks that prevented patients from initiating treatments if several critical steps were not completed within a certain time frame. Incomplete critical items such as pathology reviews, treatment consent, availability of approved prescriptions, and treatment plans in this “admissible time frame” culminated in the assignment of a “no-fly” delay and were flagged accordingly in their patient tracking system. Although their outcomes were not tested for statistical significance, they reported reduced numbers of computed potential no-fly delays per month from 60 to 20 over a total of 520 cases (57).

Similarly, Egan et al. (2012) conducted a SS project to identify issues causing once daily gentamicin dosing drug administration errors and developed data driven solutions that included developing a new dosing and monitoring schedule, and standardized assay sampling and drug administration timing that focused on improving dosing and performance monitoring. Their project improved the attainment of serum levels sampling in the required time window by 85% ($P<.0001$) and also documented a 66% improvement in accuracy of dosing ($P<.0001$) (58).

Lastly, Chan (2004) conducted a SS project to improve medication-dispensing errors. The project team used process mapping and data analysis to identify dispensing error root causes and determined that human factors such as staff attitude, knowledge, and experience were key factors that caused dispensing errors. Their interventions included a SOP with improved operating procedures and educating the pharmacy staff on the improved processes, which resulted in reducing dispensing errors at an outpatient clinic pharmacy from a historical average of 338.8 to 230 errors per million opportunities, albeit their outcomes were not tested for statistical significance (59).

Defect and error reduction in Transfusion Medicine

One project was identified that reduced defects and errors in Transfusion Medicine. Neri, R et al. demonstrated that SS methodology could be successfully utilized to identify critical issues that caused blood wastage and generate innovative solutions that reduced blood transfusion errors. Although their results were not tested for statistical significance, Neri et al. reported in 2008 that their project reduced inappropriate transfusions of packed Red Blood Cells from 16% to 5% which saved approximately $121,000 in 2005, through interventions that improved the clinician's use of a blood component order form, established internal performance benchmarks, enhanced the lab to clinician communication, and through better blood product expense control (60).

Defect and error reduction in Transplant Surgery

One SS project, published in 2012, was conducted in a Transplant Surgery department with the aim to prevent defects that caused post-operative hyponatremia in a renal transplant population. Leaphart and colleague's SS project utilized the fishbone diagram to identify potential causative factors that contributed to abnormal serum sodium levels in the acute postoperative period. The team determined that the method of dialysis might cause low postoperative serum sodium. Additionally, it was found that the current team of transplant anesthesiologists did not favor the hospital's policy of 0.45% sodium chloride as data revealed that 92.6% of 54 renal transplant patients were hyponatremic in the postoperative period. The team developed mitigating solutions such as a new policy change to double the administering of sodium chloride during renal transplantation to .9%. Their project achieved low serum sodium levels of 7.8% among the renal transplant population, surpassing their initial project goal which was to reduce abnormal serum sodium levels from a baseline of 92.6% to <10% (P<.0001) (61).

Defect and error reduction in an Automated Lab

One project demonstrated the reduction of analytical errors and defects in an automated pathology lab. Riebling et al. demonstrated that they were able to utilize the SS methodology to identify root causes and generate solutions such as improved staff training, simplified lab results review guidelines, and a modified auto-verification process to capture real time flags for suspected incomplete blood count orders. Though the outcomes were not tested for statistical significance, the article noted that their solutions improved the volume of the lab orders processed and improved their sigma level from 4.8 to 5.0 (62).

Improving quality of care and patient satisfaction

Eight articles (18%) described projects designed to improve various dimensions of quality of care and patient satisfaction.

Improving quality of care in perioperative workflow

One LSS and one SS project were conducted in academic tertiary care centers to improve quality in the perioperative process. In an effort to reduce post-operative infections, Parker and colleagues in 2006 conducted a SS project that improved adherence for antimicrobial prophylaxis within 60 minutes of incision. Their interventions included reinforcements of use of standardized preoperative order forms, eliminating the administration of antibiotic prophylaxis in the surgical admissions preoperative area, and sending antibiotics with intravenous tubing to the operating room. The article reported a significant improvement with an increase from baseline of 38% adherence for 615 surveyed surgical procedures pre QI project to 86% adherence for 1716 procedures surveyed post intervention ($P<.01$).

Additionally, the interval for antibiotic administration before surgical incision also decreased from a pre-intervention mean of 88 minutes (CI 56-119 minutes) to 38 minutes (CI 25-51 minutes) ($P<.01$) (63). In another perioperative project, Martinez et al. in 2011 published an article for a LSS project which developed a formal glucose control protocol in the operating room and instituted a nursing education intervention on controlling glucose levels to achieve glycemic control in cardiac surgical patients to improve outcomes. Their interventions significantly increased the average number of glucose measurements per patient per day from 3(±4) to 12(±4) ($P<0.001$) and also admission glucose of <200 mg/dl increased from 76% pre-intervention to 94% post intervention ($P<0.001$) (64).

Improving quality of care and patient satisfaction in labs and medication use

Four QI projects demonstrated usefulness in improving health care quality in medical labs and medication use processes. Yamamoto and colleagues produced two articles in 2010 demonstrating the use of LSS to improve medication use in an academic tertiary care center setting. In one project they improved the timing of inpatient insulin administration related to meal delivery for patients awaiting radiological testing by identifying root causes that included diabetic food order errors, inconsistent food delivery times, and inconsistent timing of blood glucose tests; and implementing interventions that included a standardized food delivery schedule, scorecards to track on-time meal deliveries, better communication between nursing and food service staff, and restricting the schedule of inpatient procedures during mealtimes. Although tests for statistical significance were not conducted on the results, the interventions were reported to have reduced the proportion of patients with low blood glucose levels within range, from baseline 1.1% of patients experiencing low blood glucose levels (<50 mg/dL) and 23.2% of patients experiencing high blood glucose levels (>180 mg/DL) to .8% (<50 mg/dL) and 20.4% (<180 mg/dL) respectively. They also met LSS project goals of 95% of meals delivered within ±15 minutes of the scheduled time with 97.6% on-time meals, and 100% of inpatients having radiology services scheduled in the "green" which meant that radiology tests were scheduled during acceptable times that excluded one hour periods for breakfast, lunch, and dinner (65).

Yamamoto et al. also conducted another project to improve the insulin dispensing and administration process using LSS. This team identified seven factors that impacted dispensing efficiency: (1) limitations in manpower; (2) lacking or inconsistent following of SOPs; (3) staff actions that could risk patient safety: (4) inconsistent timing of doses, meals, and tests; (5) misplaced medications; (6) lack of communication among medical floors, pharmacy, and food service staff; and (7) limitations of information technology. Interventions to address these root causes included checking medications centrally instead of at satellite pharmacies, adding additional insulin and associated supplies to automated dispensing cabinets on each floor, and replacing shared bins for medications with separate storage bins for each patient. These interventions were reported to have improved the medication dispensing process, resulting in significantly fewer patients experiencing blood glucose levels over 180 mg/dL 23.2% compared to 20.4% (P=.0008). Additionally, compared to pre LSS project intervention, significantly fewer patients experienced blood glucose levels less than 50 mg/dL (1.1% vs. .8%, P=.0155) (66).

Calhoun and colleagues used LSS to improve the tracking and quality of Pap smear and critical pathology results. This team determined that lacking standard means to track pathology results was a key factor and implemented solutions that included standardizing and automating workflows which resulted in error proof handling of all critical Pap smears and abnormal findings. The interventions resulted in significantly improving on the number of Pap smears outside of the 7 day criteria from 5.3% in 2008 at baseline to 2.6% (P<0.008) in 2009 post intervention (67). Elberfeld et al. published a LSS project in 2004 that demonstrated improvement in the quality of cardiac medication administration. The team identified physician documentation and clinical practice, nursing practice, clinician's knowledge of core measures, paramedic involvement, documentation of care delivery and contraindications, and emergency department operations as potential causes for variation. The team implemented intervention strategies that included physician and staff education, stocking aspirin on each hospital floor, and shortening the form that paramedics needed to complete. Although the intervention outcomes were not tested for statistical significance, the article reported that the interventions resulted in meeting all Centers for Medicare and Medicaid Services indicators (68).

Improving quality of care and patient satisfaction in Internal Medicine and a medical outreach program

Two articles revealed that LSS could be used to improve quality in the Internal Medicine department. Neufeld and company in 2012 demonstrated that LSS could be used to improve the discharge process. Their LSS project determined that a computer-generated discharge plan (CGDP) was better at creating more complete discharge worksheets than the baseline process of a provider generated discharge plan (PGDP). The new process that included the use of the CGDP improved compliance of discharge paperwork completeness from 61.8% to 94.2% (P<.0001); and also improved the percentage of charts that were 100% complete from 11.9% to 67.8% (P<.001). Meanwhile, Dupree and colleagues reported in

2009 that SS was used to improve pain management. The team determined that when staff asked the patients about their pain, displayed concern and care about the patient's pain, and provided prompt response to the patient's pain, overall patient pain management satisfaction scores were significantly impacted (P<.0001). Although a test for statistical significance wasn't conducted on the outcomes, the article reported that the interventions resulted in overall pain management "Excellent" ratings increases from 37% to 54% and both the medicine and surgery units surpassed their goals of having at least 50% of responses being in the "excellent" rating (70).

Beard and colleagues reported on a SS project in 2008 that improved clinical outreach to patients with depressive disorders. This SS team identified that "no telephone answer" and "no telephone number in the member database" were key barriers impacting clinical outreach. The team implemented a policy for care managers who were located in the Pacific time zone to call members in the Eastern time zone between the hours of 2 pm and 5 pm and increased call backs from one to four; and utilized images from claim forms to update member telephone numbers. These interventions had a statistically significant improvement that increased outreach percentage from a baseline of 7% to 20% post intervention (P=.000) (71).

<u>Improving public health through increasing immunization rates</u>

One LSS project published by Hina-Syeda et al. in 2013 examined how to improve public health by improving immunization rates against pneumonia and influenza prior to immunization being implemented as a core measure in the metro Detroit area. This project was accepted as an Alliance of Independent Academic Medical Centers (AIAMC) National Initiative (NI) III project. The project team used tools such as the fishbone diagram, and FMEA, to identify high-risk vaccination processes and systematically mitigate them. Improvements included revising assessment forms; developing Electronic Medical Record backup procedures; and creating improved overall vaccination processes. Although the article did not provide statistical significance of pre-post intervention outcomes or compare results to a comparison group, the authors reported that the project improved immunization compliance from a baseline z score of 1.96 and a yield of 67.7% to post intervention z score of 3.9 with a yield of 93.5% (72).

Cost Reduction

A SS and LSS project was identified that improved the hospital's financial health by focusing on cost reduction. Elberfeld et al. described a cost reduction project in 2007 that primarily aimed to improve accuracy of the Home Health Related Group that determines a payment group assignment for services. The team converted the manual processing of the Home Health Related Group (HHRG) to an automated process that significantly improved their HHRG case-weight mix from 1.07 to 1.26 (P value=.042). Although the article did not state how the cost savings were calculated, it stated that the improvements helped them achieve $1.2 million in cost savings for the first year (73). Pocha, et al. conducted a LSS project in 2010 that aimed to reduce the number of unnecessary portable chest x-rays in the emergency room. The team determined that approximately 30% of all portable x-rays in the emergency department (ED) will be repeated as two view poster anterior/lateral (PAL) x-rays within 24 to 48 hours for the same indication and therefore can be avoided. Therefore, this LSS team implemented a policy to only conduct PAL chest x-rays on patients arriving in the ED if no contraindications exist. Although a test for statistical significance had not been conducted, the article stated that improvements had a 9% reduction in chest x-rays in the ED. They estimated that their improvements have reduced approximately 588 chest x-rays per year, and at an unrecoverable cost of $17.52 per x-ray, they estimated a yearly savings between $5,974 and $10,303 dollars, depending on ED volume load (74).

2.5 Discussion

Through this systematic review, we found that SS/LSS methodologies have been used successfully in many different aspects of health care in clinical and non-clinical settings around the world; successful projects have been completed in clinical departments such as surgery, internal medicine, and emergency medicine to standardize clinical processes, reduce defects, improve cycle times, and improve health care quality across many different clinical and administrative processes. We also found that SS/LSS projects have been successfully executed across many different health care settings, including large academic tertiary hospitals, smaller community hospitals and public health settings. Additionally, there were projects for which the main purpose was to reduce cost, and several other projects that yielded cost reduction as a positive byproduct.

It is worthwhile to point out that the majority of the QI projects (68%) in our study were conducted in an academic tertiary care center setting. This may be due to the fact that SS/LSS projects require initial investment to train participants in the

SS/LSS methodology and/or to hire SS/LSS experts to provide project mentorship. Since funding for management research is not a priority for many health care organizations (76), this upfront cost to develop SS/LSS capability may only be able to be afforded by large academic institutions, sometimes through grants from public and private funding that non-academic health care organizations don't have access to. Additionally, academic medical centers represent innovative institutions with a culture of leading research, thereby seemingly a natural setting for conducting and publishing SS/LSS projects in biomedical journals (76). As academic medical institutions lead the way in evaluating the effectiveness of SS/LSS in health care, there are opportunities for other health care organizations to collaborate and partner with health researchers to expand adoption of SS/LSS in health care.

Another worthwhile discovery is that the largest number of reviewed articles aimed to reduce cycle time, which reflects the original concept of the Lean Thinking philosophy of optimizing the flow of products and services by eliminating waste along entire value streams. Therefore, it was not surprising to find more projects used the LSS methodology to conduct cycle time reduction projects (*Table 3*). On the other hand, defect reduction was the second most frequent project aim, which is actually the main idea of SS that strives to reduce errors to only 3.4 DPMO by systematically applying a disciplined, data-driven approach and methodology for eliminating defects. Again the findings from our review support this as more than twice as many defect reduction projects leveraged the SS methodology (*Table 3*). However, in projects that aimed to improve quality and reduce costs, both QI approaches were evenly utilized. These patterns may reflect the recent phenomenon that in other industries SS has been absorbing the Lean Thinking, and health care is no exception in harnessing the fruits originating from both methodologies.

Although the specific aspects of each project varied considerably, our review suggests that SS/LSS projects in health care are generally being conducted for repeatable processes that could benefit from process standardization. A repeatable process is defined as a set of actions that can be easily duplicated (9). For example, 42 out of 44 articles (*Table 4*) we reviewed conducted projects on processes that were considered easily duplicated, such as medication dispensing, diagnostic imaging, and the referral management processes. Specifically, a health care example in which SS/LSS was used to improve a repetitive process was standardizing CHF order sets to reduce hospital LOS and implementing standard clinical pathways to reduce LOS in surgery cases. Two projects that were not considered easily repeatable in our study were based on efforts trying to change hand hygiene behavior of hospital staff. This finding is in line with the design intent of SS/LSS that was developed originally in the manufacturing field with many repetitive processes.

The above-mentioned findings suggest that SS/LSS methodologies can be applied to a variety of problems in health care that are seemingly not related. Furthermore, the applicability stresses that SS/LSS is a problem solving methodology and not a specific solution methodology for a certain problem. This gives SS/LSS great strength and potential to positively impact health care, but at the same time raises questions of its efficacy as well due to the fact that building a solid empirical evidence base of the effectiveness of SS/LSS is rather difficult. Indeed, we began with 985 articles and finally narrowed down to 44 unique projects in which the health care environment of the SS/LSS projects varied significantly. Additionally, what complicates proving the effectiveness of SS/LSS is that those 44 projects utilized different tools and techniques to identify root causes. To illustrate, for finding root causes, in addition to the most commonly used fishbone diagram (also known as the Ishikawa or cause and effect diagrams), fault tree analysis or even FMEA can be utilized (77) (78). Developing solutions is even more variable; some prefer simple ‘double check’ methods, but others may choose a complete overhaul of the process and replacing it with an automated system. As such, the roles and expertise of the SS/LSS leader is extremely essential and cannot easily be standardized, which makes measuring effectiveness of all SS/LSS projects difficult.

In addition, we also have to be cautious in determining the effectiveness of SS/LSS in health care. Even though the studies met our inclusion criteria, the sample size was small; beyond that, many of the articles that were reviewed did not provide rigorous study designs with statistical analysis. Only three studies designed a comparison group analysis to determine whether the improvement came from the intervention itself and was not a result of confounding variables or secular trends. Just a little over half (N=23) of the articles provided the statistical significance of pre-post intervention differences. Additionally, the evidence collected lacked consistency in reporting that created a lot of variation in what and how the information was presented.

Finally, although we were able to identify 44 successful projects that have been implemented across different health care areas, we reviewed only the published successful projects and did not find any unsuccessful SS or LSS projects that reported negative results. Nevertheless, this potential publication bias does not apply solely to SS/LSS projects; indeed, any systematic review of published projects utilizing any methodology shares the same risk. This may also be because project failure is perceived to be due to scope or resource challenges and not the methodology itself. The absence of failed QI projects may reflect publication bias and overstate the perceived effectiveness of SS/LSS in health care or may not provide valuable lessons learned for investigators who are considering implementing these QI methodologies in their organizations. Due to these considerable limitations, the evidence of SS/LSS applicability in health care as a whole could not be adequately confirmed.

This review provided some evidence that SS/LSS can have a positive impact in a wide variety of health care areas, however it also confirmed the finding from previous literature reviews conducted on SS/LSS that there are significant gaps and weak evidence in the SS/LSS literature to confidently conclude that these QI approaches can improve health care. Nicolay et al. in their systematic review of QI methodologies for surgery hypothesize that one reason why the QI literature did not provide strong statistical evidence may be due to the fact that some article authors were from groups that were not a part of the original project teams but rather writing up QI project reports from secondary information (79). This is an interesting hypothesis that may have some merit as many article authors seemed to be clinicians, while many of the SS/LSS project mentors were not. This may be a common contributor to the reason why we found a high variation in the format and quality in the way the project articles were reported as well. To mitigate this potential issue, there is a need for a common framework that can be used by all project team members regardless of their professional or educational background to be able to effectively develop SS/LSS project reports with biomedical rigor that are acceptable for health care peer-reviewed research and publication.

In order for researchers to use the SS/LSS literature as evidence, the quality of these articles must be at a higher level to reasonably satisfy internal and external validity. DelliFraine et.al in their comprehensive review of the SS/LSS literature also agrees that the quality of the articles was poor and does not provide concrete evidence of effectiveness in health care (26).

2.6 Conclusion

This review identified that SS/LSS methodologies can be effective in improving health care performance in a variety of settings, however it also demonstrated that there are significant gaps in the health care literature and very weak evidence to ascertain that these QI methodologies are efficacious in improving health care. Although there certainly is potential for utilizing SS/LSS in a variety of health care applications to improve quality, reduce errors, and decrease costs, there needs to be more solid evidence for researchers to conduct future empirical assessments.

As health care workers, some of whom moved to the health care field from other industries, continue to work on improving quality and safety of care utilizing SS/LSS, their efforts should be effectively shared and become building blocks of collective knowledge of SS/LSS in health care to expedite the diffusion of the QI methodology across the health care system. To do so, their efforts must be published in academic journals, especially medical journals that doctors and nurses read. Otherwise their improvement efforts will last only as fragmented successes at best. Unfortunately, we found in this review that many of the peer reviewed SS/LSS articles showed suboptimal quality in meeting academic standards. To overcome this situation, there is a need for a standard SS/LSS reporting format leveraging QI reporting best practices so that future SS/LSS evidence can provide the rigor required to increase reporting quality. This will ensure that future SS/LSS project articles will be reported with the necessary elements required to provide the most research value.

3. Chapter 3: Assessing the Quality of Articles Examining the Utilization of Six Sigma and Lean Six Sigma in Health Care

3.1 Abstract

Objective: Six Sigma and Lean Six Sigma (SS/LSS) methodologies for performance improvement have been actively adopted by many health care settings. However, not much evidence of their effectiveness has been established. This study aims to review SS/LSS articles published in biomedical journals and to assess whether these articles are of sufficient quality to provide evidence regarding the effectiveness of these approaches in health care.

Design and Methods: SS/LSS articles published from 1990 to 2013 were included in this study. To evaluate these articles, a team of SS/LSS experts developed an instrument by modifying the Appraisal of Guidelines for Research and Evaluation version 2: (AGREE-LSS). Three reviewers independently assessed each article using AGREE-LSS over 6 domains and 2 final assessment items with a 7-point Likert scale. The domain and total AGREE-LSS scores were calculated and compared over time (publication year).

Results: Among the 985 articles initially retrieved, 43 met our inclusion criteria and were reviewed. Quality of the articles, which was assessed using the AGREE-LSS instrument, showed a mean composite overall assessment score of 58.00% (95% CI: 53.00%-72.95%) with 22 (52%) of the articles scoring <60% out of a possible 100%. Domain 1 "Scope and Purpose" scored the best of all the domains with a mean score of 78%. Domain 2 "Stakeholder Involvement" and Domain 4 "Clarity of Presentation" all had mean scores in the "requires additional work"

range, 65% and 69% respectively. Domain 3 “Rigor of Development”, Domain 5 “Applicability”, and Domain 6 “Editorial Independence” all scored below 60%, which represented “unacceptable” grades. A regression analysis comparing the average overall assessment scores across the article publication years (2004 to 2013) revealed that there was significant improvement in the quality of these articles, ($p<.001$).

Conclusions: Although the quality of SS/LSS articles has improved over time, limitations of the articles still exist. Many articles fail to provide concrete outcomes data, to perform statistical analysis, and to clearly describe sustained improvements, thus limiting their benefits for health care settings. Also, there was large variation in the style of these published articles, albeit they were all peer reviewed. We can improve and control the quality of SS/LSS articles by utilizing a standardized format to present evidence more convincingly.

3.2 Introduction

The cost of medical care is increasing at an unsustainable rate worldwide (15). A significant percentage of these cost increases are due to the aging population and investments in new technologies and drugs to improve health care. Another significant source of health care cost can be attributed to operational inefficiencies that cause waste, defects, and even medical errors (15). Indeed, reducing such inefficiencies is one of the most important challenges that health care is facing.

Fortunately, many other industries such as manufacturing have developed a variety of tools and methodologies to improve inefficiencies, and some of them have been applied to health care. Two of the most promising methodologies that have successfully been embraced by health care settings are Lean Thinking and Six Sigma, both of which provide a systematic approach to problem solving and improving repeatable processes. Lean Thinking emerged in Japan with Toyota leading the way in the automobile industry after World War II (7) but a systematic manufacturing productivity approach can be traced back to Henry Ford and his invention of the automotive assembly line (80). Similarly, the Six Sigma process improvement methodology was born in the manufacturing field and originally introduced by Motorola to improve product quality but was deployed as an enterprise quality culture movement by General Electric in the mid-1990s. These process improvement approaches are the synthesis of a series of the century long development of quality improvement (6). Lean Thinking and Six Sigma have gone through parallel developments over the course of the last half-century.

Lean Thinking

Lean, as it is often called, represents an integrated system of principles, tools, practices, and techniques focused on reducing waste, synchronizing workflows, and managing resources to optimize efficiency and improve cycle times. Lean embraces a continuous improvement strategy that supports more visual forms of problem identification and creating simple and direct pathways and eliminating rework and bottlenecks in the system. Lean's strength lies in its set of relatively simple standard solutions to common challenges (7). Due to the simplicity of conducting Lean projects, most lean projects do not require a complex team structure and can be executed relatively quickly. Some argue that since Lean lacks a comprehensive root cause analysis in its approach, Lean is limited to producing quick fixes and is not suitable for bigger and complex issues that require precise solutions. Additionally, since Lean doesn't incorporate a monitoring and evaluation process, it is difficult to control and sustain the improved process (12). Many view these criticisms as fair, especially in health care where every procedure should be evidence based; a criterion which requires a much more robust and standardized way of reporting improvement results, including both how Lean was used and how it reduced inefficiencies.

Six Sigma

Six Sigma is a highly data-driven process improvement methodology with strong emphasis on developing solutions to key enterprise challenges based on quantitative analysis. Six Sigma projects aim to reduce defects and variation in a process by utilizing a prescriptive five-step problem solving methodology (6): Define, Measure, Analyze, Improve, and Control (DMAIC). As Stamatis states in his book "Essentials for The Improvement of Healthcare Using Lean & Six Sigma" – Six Sigma is similar to that of good medical practice used since the time of Hippocrates (81) – relevant information is assembled followed by careful diagnosis, then treatment is proposed and implemented, followed by monitoring and evaluation to see if the treatments are effective. Although the data driven approach of Six Sigma creates the most evidence based solutions of the two QI approaches; Six Sigma's limitation lies in its robust methodology (15): Some argue that many process challenges can be improved with simple common solutions and do not require the robust data-driven DMAIC methodology (12).

Lean Six Sigma (LSS)

LSS was developed to take advantage of the strengths of both approaches: the robust process improvement DMAIC methodology from Six Sigma and simple and quick fixes offered by Lean Thinking. Through capturing the benefits of both approaches, LSS consists of principles, tools, and techniques that provide a more robust approach to process improvement and allow QI practitioners greater flexibility in addressing many different process challenges (12).

Evidence from Six Sigma and Lean Six Sigma (SS/LSS) Projects in the Health care

As clinical medicine requires evidence for a new treatment, so too do new approaches to improving health care processes and assessing their efficacy. The health care industry has been experimenting with SS/LSS for nearly two decades and evidence on effectiveness has been accumulating in the form of published peer reviewed journal articles. These have shown some evidence that SS/LSS provides positive benefits in improving health care; however, the approaches do have limitations (26) (79) (82) (83).

During our literature search, we identified four comprehensive literature reviews that evaluated SS/LSS articles for their applicability to health care (26) (79) (82) (83). All four literature reviews searched health care databases for articles and used a scoring mechanism that the authors developed to assess the effectiveness of SS/LSS in health care. These literature reviews concluded that although peer reviewed articles provide some evidence on potential applications of SS/LSS in health care, the vast majority lack concrete outcomes data with statistical analysis and therefore do not demonstrate sustained improvements benefitting health care (26) (79) (82) (83).

Furthermore, Nicolay et al. state that the evidence from peer reviewed articles is generally of suboptimal quality and needs a more standardized approach to the reporting of results in order to bring evidence based management into the same league as evidence based medicine (79). As Glasgow and colleagues state, the true impact of these approaches is difficult to judge from the current population of SS/LSS articles given the lack of rigorous evaluation, and the lack of clearly sustained improvements provides little evidence supporting broad adoption (82). More high quality information is required to bolster the evidence base for understanding more about how out-of-healthcare industry QI approaches such as SS/LSS can impact health care and achieve sustainable improvements (82).

It appears evident that previous SS/LSS systematic reviews determined that the results of this literature are inconclusive and fail to support the full adoption of these methodologies in health care due to weak study designs, gaps in reporting quality, and small sample sizes. However none of the systematic reviews evaluated the cause of what they perceived as gaps or suboptimal literature quality. Past literature reviews were conducted by developing evaluation criteria based on the strength of the study methods and outcomes data, but they did not look at evaluating the quality of reporting itself. It is possible that the vast majority of these published SS/LSS articles may have sound methods and statistically rigorous outcomes data, but did not report them due to SS/LSS project managers not having experience in writing biomedical journal articles. It is possible that the

DMAIC SS/LSS methodology is rigorous enough to provide evidence and does not require a robust research design such as a randomized controlled trial to prove effectiveness. As such, SS/LSS project reports may not lend themselves to fit the structure of a biomedical journal and may require a novel approach to assess their value in health care. As Dr. Wachter states in his book, methods to develop evidence-supported practices for quality improvement projects became prevalent in the 1990s, yet, two decades later, significant gaps persist in translating the best evidence into practice (84).

Additionally, projects are not being used to replicate best practices because they are poor in diffusing key evidence and thus are not leveraged to promote health care quality. Therefore, the aim of this article is to examine the literature concerning QI methodologies from industry – SS/LSS – and assess whether out-of-health care industry tools and methodologies were reported in peer reviewed articles with the appropriate biomedical/research rigor necessary to provide evidence of effectiveness in improving and promoting health care quality. Furthermore, we would like to expand on the current literature reviews that have been done and investigate where the gaps in reporting exist in these journal articles. Thus, we aim to review the evidence of SS/LSS in health care and try to suggest how the evidence itself or the way of presenting evidence can be improved.

3.3 Methods

SS/LSS article collection method

The authors gathered published studies from peer-reviewed journals that met the inclusion criteria. We restricted peer-reviewed articles to be in English only but did not restrict country of origin. The articles were collected from the following databases with search date ranging from 1990 to 2013: Embase, PubMed, the Cochrane Database of Systematic Reviews, ProQuest. The date last searched was January 10, 2014. The authors used the search terms that were devised to cover health care and the names and synonyms of the quality improvement (QI) methodologies: SS/LSS. They included each of the terms: ''Six Sigma*'', ''Lean Six Sigma*'', ''Lean*'', combined with the Boolean operator 'AND' with each of the following terms: ''process* improvement'', ''toyota production system'', ''6 sigma'', ''lean process*'', ''lean thinking'', ''lean sigma'' in the title or abstract.

The criteria for article inclusion were: article was published in a peer-reviewed journal; article described a study involving hospital based health care quality improvement; article described LSS or SS methodology (the intervention; see above); and the article described the conduct of an original study. Studies were excluded if: the article was a conference abstract, editorial, commentary, opinion, audit or review; the SS or LSS article did not adequately describe how the QI project used the prescribed SS/LSS DMAIC methodology; the population studied was non-health care based; or the article did not provide outcome data. The three reviewers decided article eligibility independently in a standard manner. Reviewer disagreements were resolved by achieving consensus among all three reviewers over videoconference. If an abstract was not available or did not provide enough information regarding inclusion criteria, the full-text reference was accessed. Information from the journal abstracts was collected and tabulated independently by two reviewers on to a data extraction sheet (Microsoft Excel 2010; Microsoft Corporation, Redmond, Washington, USA), guided by the Cochrane Handbook Part 2 that provided instruction on defining the study questions, developing criteria for including studies, planning the search process, and designing data collection forms and collecting the data (30).

SS/LSS quality reporting tool AGREE - LSS

Health care LSS experts (Master Black Belt and Black Belt) were asked to review existing instruments and make suggestions for potential modifications to existing tools for assessing the quality of SS/LSS articles. Instead of coming up with an arbitrary measure to score the quality, we reviewed a variety of validated tools to evaluate articles so that our SS/LSS article assessment can be compared to other published manuscripts evaluating other types of health care interventions. The Appraisal of Guidelines for Research & Evaluation (AGREE) version 2 tool was chosen as a backbone for our evaluation method. The AGREE II instrument is a validated questionnaire that was developed and used internationally to address the issue of variability in the quality of clinical practice guidelines (CPGs) by assessing the methodological rigor and transparency in which a guideline was developed (85). Aside from the benefits of utilizing a validated tool, we chose to use the AGREE tool as the basis for our assessment because just as CPGs are a means to provide standardization of treatment processes, SS/LSS projects essentially improve the current state of processes and also aims to make them standard practice. In that sense a tool for assessing the quality of CPGs is an ideal instrument to evaluate SS/LSS articles that provide the evidentiary base for health care QI practitioners just as clinicians rely on quality CPGs to perform evidence based medicine.

Based on the AGREE II instrument, the LSS expert team of this study developed the AGREE-LSS by slightly modifying some of the original AGREE II instrument assessment questions to make them appropriate to review QI journal articles rather than CPGs. The AGREE-LSS instrument mirrors the AGREE II tool and comprises 24 items organized into the original 6 quality domains:

- Domain 1. *Scope and Purpose* are concerned with the overall aim of the QI project; the specific health care related problem statement questions that frame the opportunity for the QI project; and the intended target population that the interventions from the QI project will impact (items 1-4).
- Domain 2. *Stakeholder Involvement* focuses on the extent to which the QI project was developed by the appropriate QI practitioners and represents the views of its intended stakeholders (items 5-7).
- Domain 3. *Rigor of Development* relates to the approach and methods used to gather and synthesize the root causes of health care challenges, the methods to formulate the recommendations, the assessment of the interventions benefits and potential risks, and control mechanisms to update and revise interventions to ensure sustainability (items 8-15).

- Domain 4. *Clarity of Presentation* deals with the language, structure, and format of the QI project report (items 16-18).
- Domain 5. *Applicability* pertains to the likely barriers and facilitators to implement process improvements, strategies to improve stakeholder buy-in, and resource implications of applying and sustaining the improvements (items 19-22).
- Domain 6. *Editorial Independence* is concerned with the formulation of recommendations not being unduly biased with competing interests (items 23-24).

The AGREE-LSS also includes 2 final overall assessment items that requires the appraisers to make overall judgments of the QI report after considering how they rated the 24 items individually.

Calculating and Assessing Domain and Overall Assessment Scores

A domain quality score was calculated for each of the six domains, which were independently scored by three reviewers. Domain scores were calculated by summing up all the scores of items in the domain and by scaling the total as a percentage of the ***maximum possible score*** for that specific domain. Means and 95% confidence intervals for each domain and overall scores were calculated. In addition, regression analyses were conducted to investigate the change of domain and overall assessment scores over the time period of the study.

Interpreting Domain Scores

Although the domain scores are useful for comparing SS/LSS project journal articles and will inform whether an article should be recommended as a reference, the AGREE Consortium has not set minimum domain scores or patterns of scores across domains to differentiate between high quality and poor quality. Therefore, the domain scores only provided a general guide as a percentage of total possible points for each element to assess article quality, with higher percentages being better. The AGREE instrument does not determine a priori the scores for defining quality; it is up to the researcher to decide which cutoff point to use. We used an arbitrary but generally utilized academic grading scale for the domain and overall score to assist in determining the quality of the SS/LSS articles. Therefore, a ***domain score*** greater than 90% represented "outstanding", 80% to 89% represented "good", 70% to 79% was "fair", 60% to 69% represented "requires additional work", and any score under 60% was considered "Unacceptable". Whereas, an ***overall article assessment*** greater than 90% represented "strongly recommend", 80% to 89% represented "recommend", 70% to 79% was "recommend with modifications", 60% to 69% represented "cautiously recommend with significant modifications", and any score under 60% was considered "do not recommend".

SS/LSS reporting quality assessment method

Three reviewers assessed each article independently and scored each of the AGREE-LSS instrument items and the two global rating items on a 7-point scale (1–strongly disagree to 7–strongly agree). The overall agreement among the reviewers was evaluated using the intra-class correlation coefficient (ICC). The

ICCs for the reliability of mean scores for the six domains were 0.86, 0.82, 0.80, 0.79, 0.83, 0.86, and 0.71 and 0.74 for the two overall scores, respectively. A score of 1 was given when there was no information that was relevant to the AGREE II item or if the concept was very poorly reported. A score of 7 was given if the quality of reporting was exceptional and where the full criteria and considerations had been met. A score between 2 and 6 was assigned when the reporting of the AGREE-LSS item did not meet the full criteria or considerations. A score was assigned for each assessment criterion based on the completeness and quality of reporting. Scores increased as more criteria were met and considerations addressed. Table 5 below is a sample of the AGREE-LSS tool.

Table 5: AGREE-LSS instrument assessment criteria

Domain	Assessment Criteria	AGREE-LSS Rating						
		1 Strongly Disagree	**2**	**3**	**4**	**5**	**6**	**7 Strongly Agree**
Domain 1: Scope and Purpose	1. The overall objective(s) of the article is (are) specifically described							
	2. The health care QI problem statement(s) covered by the article is (are) specifically described							
	3. The population (patients, providers, general public, etc.) to whom the article is meant to apply is specifically described							
	4. The scope of the health care problem that is improved in the article is clearly defined							
Domain 2: Stakeholder Involvement	5. The article development group includes individuals from all relevant professional groups							
	6. The views and preferences of Voice of the Customer (VOC) of the target population (patient, public, etc.) have been sought							
	7. The target users or "customers" of the improved process are clearly defined							
Domain 3: Rigor of Development	8. Systematic continuous process improvement methods were used to search for root cause							
	9. The criteria for selecting the root cause are clearly described							
	10. The strengths and limitations of the root cause are clearly described							
	11. The methods for formulating the improvement solutions are clearly described							
	12. The health benefits, side effects, and risks have been considered in formulating the improvement solutions							
	13. There is an explicit link between the root causes and the supporting solutions							
	14. The article has been externally reviewed by experts prior to its submission for peer review							
	15. A procedure for updating the article is provided							
Domain 4: Clarity of Presentation	16. The solutions are specific and unambiguous							
	17. Results from the solutions are clearly described and statistically significant							
	18. Key solutions are easily identified							
Domain 5: Applicability	19. The article describes facilitators and barriers to its application							
	20. The article provides advice and/or tools on how the solutions can be replicated							
	21. Resource challenges of applying the solutions have been considered and documented							
	22. The article presents error proofing, monitoring, and/or auditing systems to control the gains							
Domain 6: Editorial Independence	23. The views of the project sponsoring body have not influenced the content of the article							
	24. Competing interests of article development group members have been recorded and addressed							
Overall Article Assessment	1. Rate the overall quality of the article	Lowest Quality 1	2	3	4	5	6	Highest Quality 7
	2. I would recommend this article for use as evidence of project effectiveness	No	Yes, with modifications					Yes
		1	2	3	4	5	6	7

3.4 AGREE II Results

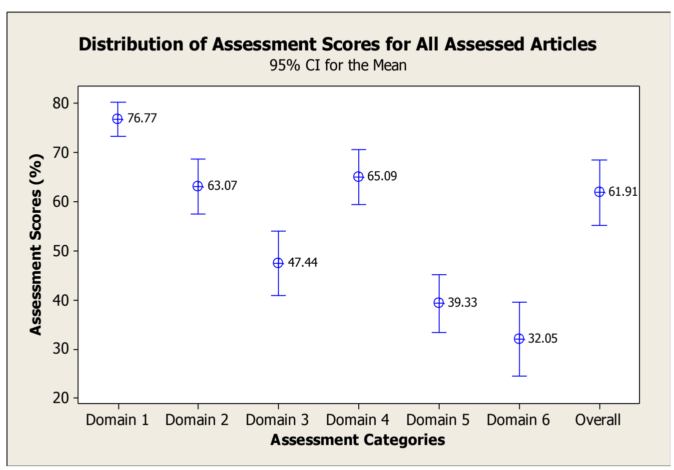
Overall Assessment Scores

A total of 985 articles were collected of which only 43 original project reports met the inclusion criteria. Three health care professionals with knowledge of both clinical workflow and LSS process improvement methodology using the AGREE-LSS standards and grading approach independently graded the 43 articles. The results displayed in Table 7 shows the AGREE-LSS domain scores and the overall scores of the 43 SS/LSS articles assessed by the three reviewers. Only four (9%) of the articles reviewed received an Overall Assessment Score of "strongly recommend" and eight (19%) were judged as "recommend". More than half of the reviewed articles (22) were rated as "do not recommend". The mean Overall Assessment Score was 61.91% (95% CI: 55.23%-68.58%).

Domain Scores

Figure 2 displays the distribution for each domain score (%) for the total assessment sample of articles. Domain 1 is designed to assess the "scope and purpose" of the QI project and determine whether the overall aim addresses the health care issue covered in the project report.

Figure 2: A comparison of the distribution of the 6 domain scores for all assessed articles



The mean score for Domain 1 was 76.77% (95% CI: 73.33%-80.20%) with three articles (7%) scoring <60%.

Domain 2 “stakeholder involvement” assesses the involvement of appropriate stakeholders, including relevant professional groups, patients’ views, and target end users of the process improvements in the development of the SS/LSS project. The mean score for this domain was 63.07% (95% CI: 57.41%-68.73%) with 18 (42%) of the articles scoring <60%.

The domain that assessed “rigor of development” was Domain 3. This domain is aimed to evaluate the SS/LSS methods used to measure and identify root causes, and develop process improvement solutions that are based on evidence gathered, and whether the health care benefits, potential side effects of the improvements, and risk have been considered. This domain also assesses the explicit link between the root cause evidence and the solutions generated to mitigate the root cause. The mean score for this domain was 47.44% (95% CI: 40.90%-53.98%) with 33 (77%) of the articles scoring <60%.

Domain 4 assessed the “clarity of presentation” aspect of the project articles. This domain aims to evaluate the degree of clarity of the article regarding the process improvement solutions implemented and to assess how easily identifiable key solutions were in the article. The mean score for this domain was 65.09% (95% CI: 59.49%-70.70%) with 14 (33%) of the articles scoring <60%.

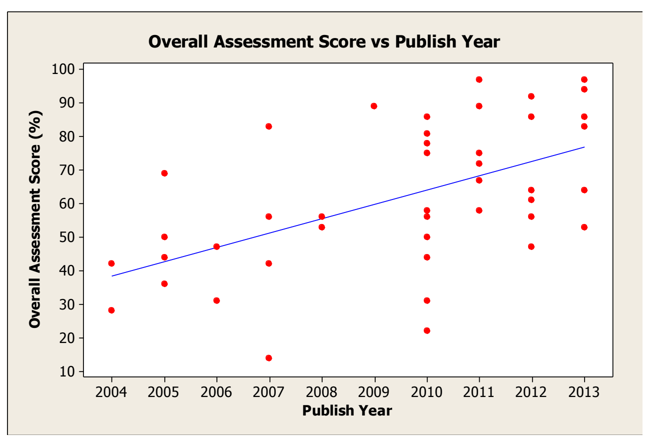
Domain 5 “Applicability” assesses whether the SS/LSS project is supported by with the appropriate resources and tools to be successful and whether organizational barriers to the implementation of the improvements have been discussed and addressed. Additionally, this domain addresses whether the costs of the solutions derived from the project are taken into account and whether appropriate control measures were implemented to monitor and/or audit the improved process. The mean score for this domain was 39.33% (95% CI: 33.46%-45.19%) with 37 (86%) of the articles reviewed scoring <60%.

Domain 6 “editorial independence” assesses the degree to which there may be bias from authors due to funding sources and the reporting of any potential conflicts of interest by the SS/LSS project group and reporting authors. The mean score for this domain was 32.05% (95% CI: 24.47%-39.63%) with 37 (86%) of the articles reviewed scoring <60%.

Changes in Quality Scores Over Time

A scatterplot (*Figure 3*) of the Overall Assessment Score plotted across the article publication year reveals an increasing Overall Assessment Score trend. A linear regression analysis was conducted to investigate the change in the average overall quality score percentage over time across the range of article publication years from 2004 to 2013. This analysis revealed that there was significant improvement in the quality of these articles (p<0.001).

Figure 3: Scatterplot of overall article assessment score vs publication year



Linear regression analyses comparing the distributions of each Domain score (%) of articles across the range of the publication years from 2004 to 203 revealed significant improvements for Domains 2, 3, 4, 5, and 6. Domain 1 “Scope and Purpose” which had high average scores at baseline, did not present statistically significant change over the assessment period. Table 6 displays this comparison analysis.

Table 6: Linear regression analysis of the Overall Assessment and Domain scores to determine whether quality significantly improved over the assessment period

Category	Coeff	Std Error	p-value	95% CI	
Overall Assessment					
Publish Year	4.28	1.02	0.00	2.22	6.35
Constant	38.31	6.30	0.00	25.59	51.02
Domain 1 "Scope and Purpose					
Publish Year	0.74	0.62	0.24	-0.50	1.99
Constant	72.67	3.80	0.00	64.98	80.35
Domain 2 "Stakeholder Involvement"					
Publish Year	2.10	0.98	0.04	0.11	4.08
Constant	51.52	6.05	0.00	39.30	63.73
Domain 3 "Rigor of Development"					
Publish Year	4.14	1.01	0.00	2.11	6.17
Constant	24.62	6.2	0.00	12.10	37.14
Domain 4 "Clarity of Presentation"					
Publish Year	3.54	0.87	0.00	1.79	5.29
Constant	45.59	5.32	0.00	34.84	56.34
Domain 5 "Applicability"					
Publish Year	3.27	0.95	0.00	1.36	5.17
Constant	21.33	5.82	0.00	9.57	33.08
Domain 6 "Editorial Independence"					
Publish Year	5.04	1.14	0.00	2.74	7.35
Constant	4.24	7.03	0.55	-9.96	18.45

Table 7: Assessing the quality of LSS and Six Sigma project articles in health care

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
Drenckpohl, D et al. (53)	Use of the six sigma methodology to reduce incidence of breast milk administration errors in the NICU	2007	64%	46%	10%	28%	3%	11%	14%
Veluswamy, R et al. (54)	I've Fallen and I Can't Get Up: Reducing the Risk of Patient Falls	2010	85%	17%	12%	70%	29%	11%	22%
Chan, A (59)	Use of Six sigma to improve pharmacist dispensing errors at an outpatient clinic	2004	76%	28%	28%	24%	33%	31%	28%
Eldridge, N et al. (49)	Using the six sigma process to implement the Centers for Disease Control and Prevention Guideline for Hand Hygiene in 4 intensive care units	2006	89%	61%	31%	56%	17%	19%	31%
Pocha, C et al. (74)	Lean Six Sigma in health care and the challenge of implementation of Six Sigma methodologies at a Veterans Affairs Medical Center	2010	81%	31%	21%	19%	0%	3%	31%
Castle, L et al. (56)	Using Six Sigma to reduce medication errors in a home-delivery pharmacy service	2005	57%	43%	24%	44%	31%	25%	36%
Bush, S et al. (38)	Patient access and clinical efficiency improvement in a resident hospital-based women's medicine center clinic	2007	74%	72%	26%	48%	7%	14%	42%

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
Elberfeld, A et al. (49)	Using the six sigma approach to meet quality standards for cardiac medication administration	2004	74%	50%	39%	46%	42%	0%	42%
Esimai, G (55)	Lean Six Sigma Reduces Medication Errors	2005	68%	65%	15%	50%	25%	3%	44%
Fischman, D (41)	Applying Lean Six Sigma methodologies to improve efficiency, timeliness of care, and quality of care in an internal medicine residency clinic	2010	64%	43%	37%	72%	32%	11%	44%
Capasso, V et al. (43)	Improving the Medicine Administration Process by Reducing Interruptions	2012	71%	65%	38%	69%	28%	17%	47%
Parker, B et al. (63)	Six Sigma methodology can be used to improve adherence for antibiotic prophylaxis in patients undergoing non-cardiac surgery	2006	76%	59%	36%	63%	50%	28%	47%
Kelly, E et al. (32)	Six Sigma process utilization in reducing door-to-balloon time at a single academic tertiary care center	2010	85%	44%	29%	54%	40%	17%	50%
Riebling, N et al. (62)	Six sigma project reduces analytical errors in an automated lab	2005	74%	57%	38%	69%	13%	19%	50%
Beard, G (71)	Improving clinical interventions through successful outreach using Six Sigma quality improvement	2008	65%	56%	33%	65%	53%	17%	53%

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
Lin, S et al. (36)	Use of Lean Sigma Principles in a Tertiary Care Otolaryngology Clinic to Improve Efficiency	2013	53%	46%	47%	83%	32%	28%	53%
Neri, R et al. (60)	Application of Six Sigma/CAP methodology: controlling blood-product utilization and costs	2008	85%	56%	40%	61%	44%	19%	56%
Chand, DV (45)	Observational study using the tools of lean six sigma to improve the efficiency of the resident rounding process	2010	69%	81%	33%	50%	22%	8%	56%
Elberfeld, A et al. (73)	The innovative use of Six Sigma in home care	2007	53%	43%	31%	48%	25%	14%	56%
Kapur, A et al. (57)	Six sigma tools for a patient safety-oriented, quality-checklist driven radiation medicine department	2012	71%	52%	44%	50%	53%	19%	56%
Calhoun, B et al. (67)	Process improvement of pap smear tracking in a women's medicine center clinic in residency training	2011	82%	70%	35%	67%	54%	22%	58%
Aakre, K et al. (44)	Quality initiatives: improving patient flow for a bone densitometry practice: results from a Mayo Clinic radiology quality initiative	2010	78%	67%	47%	65%	18%	14%	58%
Deckard, G et al. (42)	Improving timeliness and efficiency in the referral process for safety net providers:	2012	74%	54%	49%	56%	47%	47%	61%

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
	application of the Lean Six Sigma methodology								
Leaphart, C et al. (61)	Formal quality improvement curriculum and DMAIC method results in interdisciplinary collaboration and process improvement in renal transplant patients	2012	74%	39%	41%	78%	31%	39%	64%
Neufeld, N et al. (69)	A lean six sigma quality improvement project to increase discharge paperwork completeness to a comprehensive integrated inpatient rehabilitation program	2013	69%	65%	43%	44%	44%	50%	64%
Cima, R et al. (39)	Use of lean and six sigma methodology to improve operating room efficiency in a high-volume tertiary-care academic medical center	2011	72%	70%	41%	69%	57%	19%	67%
Frankel, H et al. (51)	Use of corporate Six Sigma performance-improvement strategies to reduce incidence of catheter-related bloodstream infections in a surgical ICU	2005	85%	52%	46%	61%	32%	25%	69%
Stoiljkovic, S et al. (86)	Lean Six Sigma Sample Analysis Process in a Microbiology Laboratory	2011	71%	83%	81%	72%	25%	47%	72%
Albert, K et al. (40)	How length of stay for congestive heart failure patients was reduced through six sigma methodology and physician leadership	2010	54%	80%	47%	76%	38%	44%	75%

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
Taner, M et. et al. (31)	Application of Six Sigma methodology to a diagnostic imaging process	2011	79%	70%	77%	69%	36%	28%	75%
Yamamoto, J et al. (65)	Facilitating process changes in meal delivery and radiological testing to improve inpatient insulin timing using six sigma method	2010	90%	72%	54%	76%	49%	17%	78%
Yamamoto, J et al. (66)	Improving insulin distribution and administration safety using lean six sigma methodologies	2010	85%	85%	59%	76%	39%	19%	81%
Gayed, B et al. (33)	Redesigning a Joint Replacement Program Using Lean Six Sigma in a Veterans Affairs Hospital	2013	86%	57%	82%	72%	67%	81%	83%
Fairbanks, C et al. (37)	Using Six Sigma and Lean Methodologies to Improve OR Throughput	2007	93%	89%	75%	70%	33%	28%	83%
Carbonea, C et al. (50)	A lean Six Sigma team increases hand hygiene compliance and reduces hospital-acquired MRSA infections by 51%	2010	78%	87%	58%	81%	38%	19%	86%
Egan, S et al. (58)	Using Six Sigma to improve once daily gentamicin dosing and therapeutic drug monitoring performance	2012	85%	69%	78%	81%	63%	86%	86%
Toledo, A et al. (34)	Reducing liver transplant length of stay: A Lean Six Sigma Approach	2013	79%	78%	69%	98%	39%	75%	86%

Reference	Article Title	Publication Year	Domain 1: Scope and Purpose	Domain 2: Stakeholder Involvement	Domain 3: Rigor of Development	Domain 4: Clarity of Presentation	Domain 5: Applicability	Domain 6: Editorial Independence	Overall Assessment Total
DuPree, E et al. (70)	Improving patient satisfaction with pain management using Six Sigma tools	2009	78%	85%	57%	80%	47%	47%	89%
Martinez, E et al. (64)	Successful implementation of a perioperative glycemic control protocol in cardiac surgery: Barrier analysis and intervention using lean six sigma	2011	79%	78%	56%	83%	57%	56%	89%
Niemeijer, G et al. (35)	The usefulness of lean six sigma to the development of a clinical pathway for hip fractures	2012	92%	78%	78%	94%	61%	56%	92%
Hina-Syeda, H et al. (72)	Improving Immunization Rates Using Lean Six Sigma Processes: Alliance of Independent Academic Medical Centers National Initiative III Project	2013	90%	87%	78%	72%	85%	100%	94%
D'Young, A et. al. (47)	The use of a co-design model in improving timely bleed reporting by adults with haemophilia living in the Auckland region of New Zealand	2013	98%	89%	87%	96%	74%	81%	97%
Silich, S et al. (48)	Using six sigma methodology to reduce patient transfer times from floor to critical care beds	2011	96%	93%	90%	94%	78%	64%	97%
Total Average* (rounded to nearest whole number)			**76%**	**63%**	**47%**	**65%**	**39%**	**32%**	**62%**

3.5 Discussion

The current study aims to assess the quality of SS/LSS project articles and determine whether those articles showed enough scientific evidence in their structure and content to persuade health care workers who are highly trained in an evidence-based approach. As a means to that end, a team composed of seasoned Lean Six Sigma experts with health care experience developed an instrument to review the SS/LSS articles by modifying the AGREE-II questionnaire originally developed to grade CPGs. We leveraged the AGREE II tool for our purpose because CPGs and SS/LSS project report aims are closely related. CPGs are used for disseminating evidence-based best practices, and SS/LSS projects, by solving problems and removing inefficiencies in an evidence-based and highly data-driven approach, also seek to find and disseminate the best practices. Therefore, CPGs for a certain problem can be developed by collecting evidence shown in SS/LSS project reports. In this sense, many components of the original AGREE instrument for CPGs can be directly or with small modification used to evaluate SS/LSS articles and decide whether they contribute to the evidentiary base of SS/LSS in health care.

In comparing the AGREE-LSS scores of the 43 SS/LSS project articles, it is important to note that few manuscripts presented enough research reporting quality with acceptable outcomes to suggest that SS/LSS are effective in improving health care. More importantly, the majority of the articles failed to clearly report a sound methodology, which ultimately prevents health care professionals from replicating or referencing the project. Though we identified such deficiency in the quality of the articles, it should be noted that the overall assessment and domain scores were improving over time. This may indicate that the SS/LSS as an enterprise-wide continuous process improvement program in health care has been gaining traction and maturing; and those SS/LSS practitioners are gaining more experience publishing health care projects in biomedical journals and possibly biomedical researchers are adopting and engaging in SS/LSS projects and publishing themselves.

To enhance such improvement in the article quality, this study took a deeper look into the articles by utilizing the domains of the AGREE-LSS instrument to locate where the weaknesses were and made recommendations to improve the quality of future SS/LSS articles. Thus QI practitioners can refer to the following sections as a guide to write their own SS/LSS project reports in biomedical journal article fashion.

The domain that assessed how well the article described the aim of the QI project, the specific health care QI problem statement, and the target population (Domain 1) consistently scored in the “fair” quality range throughout the articles reviewed. For most of the projects, Domain 1 is tightly linked with the Define phase of SS/LSS. Unlike the other phases of SS/LSS, which allow much flexibility in selecting tools and analytic methods to those who conduct the projects, the Define phase requires the SS/LSS team to develop a concrete project charter that identifies the problem statement and scope of the project. Despite the ‘fair’ score in Domain 1, there is much room to improve, and we suggest a more structured approach in ‘translating’ SS/LSS documents into the contents of Domain 1, which is usually described in the Introduction section of the biomedical article format of SS/LSS articles that we reviewed. First, the ‘problem statement’ or ‘business case’ in the project charter, with minimal modification, can be directly used as a piece of the background part in the Introduction section. The Supplier-Input-Process-Output-Customer (SIPOC) diagram, one of the most frequently used tools of SS/LSS can provide much richer and clearer information regarding the problem, and smoothly lead to the purpose and the goal of the project. As well, the objectives and goals section of the project charter usually contain higher resolution of information than non-SS/LSS articles, and therefore can be used as the aim of the project in the article without any modification.

One of Six Sigma’s (SS) key differentiators from other business process improvement methodologies, such as Total Quality Management (TQM), is that the SS/LSS methodology is a customer focused approach and projects begin with clearly identifying who the “customers” are and understanding their voice through gathering the Voice of the Customer (VOC). Therefore, all of the successful SS/LSS projects should have defined a target population, which is Domain 2 of the AGREE-LSS instrument. Domain 2 assessed whether the QI team included the appropriate team members or whether the target population was clearly defined and their views were collected and understood. The reviewed articles scored low and fell under the “requires additional work” category because many of the articles failed to clearly state whom the target audience was or what their views were on the issue that had been identified. This information can be placed in the background and objective of the Introduction section of a biomedical article.

Various formats are available: one might want to declare the population who will benefit from the outcomes of the project, such as a clinical outcome; another could describe who are involved in the process of interest. The contents of a Stakeholder Analysis and Force Field Analysis used in many SS/LSS projects, and a common trait of successful projects, are great sources of information that will certainly enrich the beginning of the article.

Domain 3 assessed the rigor of development, which we consider to be the most important aspect because it evaluates how a sound process improvement methodology was used to provide explicit links between the root cause and solutions. This domain scored very low with “unacceptable” quality in our assessment. Many of the articles we reviewed failed to clearly identify the methodology that was used throughout the DMAIC process. We also found that many of the articles failed to describe how they identified the root causes, to list what methods or tools were used to develop the solutions, or even to link the implemented solutions to the root cause. A few reasons for such a high percentage of non-compliance could be due to a combination of high variation of SS/LSS project pathways that are dependent on the scope of the effort with a lack of SS/LSS reporting frameworks that provide research quality standards. Domain 3 can be improved by leveraging the activities and tools from DMAIC; specifically describing the Measure, Analyze, and Improve phases in a logical sequential fashion.

For example, in the Methods section, first a brief description of the DMAIC methodology will help orient the reader to the QI approach the project is taking.

The Measure phase then should be explained in detail, particularly the process that was investigated and the input and output indicators that were evaluated to determine the root cause of the issue. The data collection plan and the data quality assurance method should be discussed in detail with a discussion of potential strengths and weaknesses of the data for identifying root causes. Also a description of the type of outputs that are expected and the analysis method that will be used to analyze the results should be included. Then authors should describe the activities and tools used to identify the root cause(s). If quantitative analysis was conducted, then a description of the statistical analysis used to identify the root cause(s) should be explained. More importantly, if quantitative analysis was not possible, any thought processes and rationale that guided the projects should be described in detail to convince the readers; root cause analysis tools such as fishbone analysis, 5-Why's, Failure Modes and Effects Analysis (FMEA), and Pareto diagrams can help, but one should be aware that these qualitative tools may provide less compelling evidence, at least as perceived by reviewers. Finally, describing the methods that were used to develop solutions that are linked to the identified root causes, such as any brainstorming methods and/or selection criteria method such as a Pugh matrix, should be explained. Providing a detailed explanation of the SS/LSS methodology with specific tools that were used throughout the Measure, Analyze, and Improve phases will help describe the study design and will assist the readers in understanding the foundation for the results.

Domain 4 assessed the extent to which the results were presented in a clear and unambiguous fashion. Though scored second highest after Domain 1, it still fell under the "requires additional work" category on average. Throughout our review, we found many of the articles failed to provide solutions that were specific and unambiguous with statistically significant outcomes data that were compared to baseline or a comparison group. The high percentage of non-compliance in this domain may be partially due to the challenge that quantifiable outcomes data from SS/LSS projects are difficult to obtain. Most SS/LSS projects, like many other QI projects in health care, require manual data collection since most projects are conducted in transactional environments with highly variable processes. Due to the high effort of manually collecting data, many projects may be conducting the Measure and Analyze phases by performing qualitative data analysis. Though meaningful on its own, such qualitative data seldom provide the type of evidence that QI projects usually require to publish in biomedical journals. Another reason for non-compliance to the review criteria may be because project authors are not experienced in translating QI results into a research journal format.

A potential solution to improve the clarity of presentation of SS/LSS projects is to develop a framework to guide QI authors on how to present pertinent information collected in the Measure and Analyze phases of the project in the Results section of the article. For example, in the Results section the authors should present the SS/LSS tools that were used to perform the data or qualitative analysis. They should also present the analysis tools that were used such as fishbone, cause and effect, and value stream map/analysis if using qualitative analysis methods or inferential statistics. They should display statistical outputs using tables and graphs such as boxplots, histograms, and scatter diagrams to represent the data. Once the data analysis approach and methods are described, they should clearly list the root cause(s) that were identified. The results from the solution generation methods that were described in the Methods section should be presented next with the key improvements clearly linked to root issues that were identified. If appropriate, a pilot study with initial results should be discussed as well as any adjustments in the project that were made. As a last step, authors should list the final results of the improvement efforts with a comparison of the output variable(s) from baseline to the improved state, preferably using statistical analysis. One of the common pitfalls that even a seasoned SS/LSS leader encounters is showing only the p value as statistical evidence. Actually, the p value is determined by the effect size and sample size, and many biomedical journals require clear descriptions of both. Thus, showing the value of interest, its confidence interval if available, and p value (for those who are not used to the issues of effect size and statistical significance) will help readers understand the result by providing more detailed evidence. Only if statistical comparisons are not available, should other means to validate improvements be described in the Results section.

The domain that assessed how well the project can be replicated (Domain 5) scored in the "unacceptable" category mainly because most of the articles we reviewed failed to include any aspects of their solution implementation and monitoring and controlling activities from their Improve and Control phases. Key elements that should be included such as identification of barriers to implementation, lessons learned throughout the project, error proofing the improved process, change management activities, and/or project knowledge transfer activities were omitted for the most part. A mature SS/LSS project would conduct error proofing or “poke yoke” as it is called in LSS to ensure that potential human errors are mitigated. A statistical process control (SPC) methodology is also implemented in SS/LSS projects to monitor the improved process with identified mitigating activities if the process is out of control. Also, lessons learned and best practice sessions with the project members are conducted during the project and documented in the Control phase that details the potential pitfalls and leading practices that can be leveraged for future project leaders who may be interested in replicating the project. Omissions of these elements could be because QI authors may have omitted monitoring and controlling activities in favor of publishing key transformation accomplishments. This is an easy fix as activities conducted in the Improve and Control phases of SS/LSS projects that correspond to how the improved processes should be controlled to sustain the gains can be easily translated and described in the Discussion section of the article.

The lowest average scoring domain was Domain 6 “Editorial Independence”. This domain, which scored low mainly because many of the SS/LSS articles we reviewed simply didn’t disclose independence from potential internal or external influence, is an easy fix as well. Disclosing whether the project sponsoring stakeholders had more than the traditional governance role in the project or whether the project members may have had competing interests are pertinent because they allow the reader to understand the project in a bigger context. Also, the authors just simply need to disclose after the study conclusion their funding sources if any for their SS/LSS project and whether there may be any competing interests from any of the article development members.

QI practitioners can benefit from the rigorous SS/LSS methodology, DMAIC, even in structuring and writing quality articles. Project members can structure the article using the five phased DMAIC framework to help the reader understand the purpose, methods and results of the project, which allows the readers to reasonably decide whether the project is applicable or replicable to their own workplaces. Accordingly, we identified four articles in our review that structured their manuscripts in this way and scored in the “outstanding” category for the domain scores and “highly recommend” for the Overall Assessment category (72) (47) (35) (48). These four articles provided “best in class” examples of how to clearly articulate the scope and public health purpose of the QI project; stakeholders and appropriate team members for the project; SS/LSS framework and how it was used as the study design; measurement plan and associated outcome metrics; and comparison of the outcomes from baseline and post intervention. These four SS/LSS articles should be leveraged as examples to create a template for other SS/LSS practitioners to use to assist them in publishing their efforts.

Poorly published reports can be a dangerous influence that may actually cause harm rather than provide positive insights to improving health care. Although SS/LSS projects develop process interventions that generally do not harm patients if applied incorrectly, as Holzmueller and Pronovost have noted, publishing unsound projects that lack methodological rigor and violate validity rules may indeed cause harm (87). If SS/LSS studies don't have the rigor and are not confidently generalizable, harm can be produced in the way of wasted opportunity costs involved in adopting the recommended interventions, where the wasted resources and attention could be applied to more pressing areas (87). Additionally the SS/LSS articles we reviewed generally lacked clarity regarding key elements that assures internal and external validity such as the study population, data collection quality assurance processes, interventions and co-interventions aligned to root issues, and outcome measures. Another weakness that must be addressed is the potential for publication bias originating from both the writers, as many organizations that perform QI projects "cherry pick" projects for publication and present them as having generalizable results, and from the journal editors as only successful projects may be selected and published, thus creating a population of published SS/LSS manuscripts that presents high risk of misinforming others (87).

To that end, creating SS/LSS specific standards and guidelines for publication that are easy to use will enable those who may not have biomedical research backgrounds to publish quality evidence. This relatively simple recommendation of developing a standard SS/LSS reporting guide based on the biomedical publishing standard IMRaD (56) integrated with the DMAIC framework may serve to improve the quality of the SS/LSS evidence while making the process applicable to SS/LSS practitioners in a way that will encourage more projects to be published.

3.6 Conclusion

The need to improve the quality of QI research to the level of evidence-based medicine is high. A push is needed for increased support for rigorous QI studies, from both external funders as well as from institutions themselves. As Pronovost and Wachter states – “better training in research methods for individuals working in the field, and more sensitivity on the part of journals and their reviewers regarding the science of QI, would help to improve the ability to publish projects with generalizable results” (87). Informed by better quality QI studies, stakeholders who are deciding to implement a QI intervention can be confident that the conclusions from the literature they are emulating could be generalizable to their own work setting (87).

However, if we assess the applicability of SS/LSS with the same rigor as we do for clinical trials, then SS/LSS QI methodologies fail to provide evidence for efficacy in health care. However, is assessing SS/LSS projects using the standard of a clinical trial that requires the use of a strong study design to mitigate bias appropriate? Since the majority of the QI projects are meant to improve processes of care and not directly intended to impact clinical outcomes, is it warranted to subject SS/LSS projects to the rigorous requirements used in conducting RCTs in order for their worth and legitimacy to be established for health care settings? This is a topic that should be further discussed to determine what value SS/LSS should be expected to bring to health care and then to develop appropriate assessment mechanisms to determine whether individual projects have met the intended goals and objectives. In the meantime, utilizing a QI reporting structure that integrates the SS/LSS DMAIC methodology and the academically accepted IMRaD format may improve the evidentiary base provided by future projects and thus serves as an accepted method of evidence that can be diffused across the health care industry.

4. Chapter 4: Determinants of Lean Six Sigma Success in Health care

4.1 Abstract

Objective: Identify central issues that prevent Lean Six Sigma (LSS) projects from achieving intended targets and sustaining the improved state in the health care environment.

Methods: Focused interviews with seven experienced process improvement experts in the health care environment serving as key informants.

Results: Key informants noted barriers that prevented LSS projects from achieving lasting success which were grouped into six themes: insufficient leadership commitment and support; lack of project alignment to health care business strategies; lack of proper investments in LSS solutions; declaring victory too soon; lack of health care business experience from LSS practitioners; and lack of data analysis and study design rigor in LSS projects. Among the various suggestions for solutions, it is most often noted that health care organizations interested in utilizing LSS need to evaluate their environment and assess whether their current organizational culture is able to implement a robust process improvement program that requires leadership to commit necessary resources with adequate training and tools to be successful.

Conclusions: Although LSS has been used in health care for nearly two decades, evidence shows that organizational barriers diminish the potential for LSS to provide breakthrough improvements. In order for LSS projects to offer lasting benefits, health care organizations must develop a LSS program with a committed

leadership that drives a mature governance structure to support process improvement projects.

4.2 Introduction

The health care industry has been transforming its operations to cut the cost of care because many believe that the current state of the health system, particularly in the United States, is not sustainable (88). The American Recovery & Reinvestment Act of 2009 (ARRA), as an example, allocated more than $147 billion to health care to target efforts to reduce waste in the system and improve efficiency, patient quality, safety, and outcomes. In fact, each of the nation's nearly six thousand hospitals must cut approximately $2.6 million a year for the next 10 years to get US health care to reach a sustainable state and meet President Barak Obama's health care reform, according to a US Today article (88). The growing popularity of the Lean Six Sigma (LSS) process improvement methodology mainly *Table 8. High Level Summary of Lean and Six Sigma* stems from this impending sustainability issue for health care settings (89); however, LSS has been used to improve clinical outcomes and patient safety as well as reducing health care costs (75).

Table 8: Brief history of Lean and Six Sigma

	Lean	Six Sigma
Began	1950s	1990s
Company responsible for methodology	Toyota Motor Company	GE/Motorola
Continuous process improvement (CPI) approach	Develop efficient processes based on principles of flow and waste elimination	Data driven approach using a five step methodology - Define, Measure, Analyze, Improve, and Control to reduce defects that cause variation
Professional certification levels	There are three lean certification levels ranked from lowest to highest - Bronze, Silver, and Gold	There are three Six Sigma certification levels ranked from lowest to highest - Green, Black, and Master Black Belt

As shown in Table 8, LSS is adopted from two process improvement techniques namely Lean and the Six Sigma. Lean originates from the Toyota automotive company in Japan and is a set of principle-driven tools and techniques used to empower the entire organization to constantly improve the processes to ensure waste is minimized, and the flow of processes is streamlined; the biggest focus is on the customers and their satisfaction (90). Lean is based on five principles including: identification of customer requirements; elimination of non-value added elements in the value stream of each product or activity; adoption of the best cultural practices that allow continuous smooth flow of the value stream; identification of process flow elements that would benefit from the “pull” technique – a technique to “pull” or receive work in a value stream in a controlled, rather than pushing work to the next value stream for work to be completed; and finally, focusing on perfecting the value chain to eliminate unnecessary steps that consume time (11). In addition, the Lean process has three stages: the stage of acceptance, the technical stage, and finally the sustainment stage where the culture has been built, but, constant review and reminding is required (91). Lean uses cross-functional management techniques through utilization of teams in a flat hierarchy of supervising managers to execute projects (92).

On the other hand, the Six Sigma methodology originated in the United States in the late-1980s in two large manufacturing based companies, General Electric and Motorola (13). Six Sigma is a systematic and robust approach to process improvement, which seeks to reduce defects that cause variation in quality through applying management tools and statistical techniques to foster improvement. This methodology relies on a prescriptive five-phased DMAIC methodology (define, measure, analyze, improve and control) to conduct the process improvement project (13; 9). Six Sigma projects are generally driven by a team whose structure is clear and each team member has a defined role as follows: a project champion sponsors a project and commits resources required to complete the project; a Six Sigma Master Black Belt is in charge of coaching and training the project team as required; a Six Sigma Back Belt leads the improvement project with overall direction; a Six Sigma Green Belt leads the execution of the project tasks; and subject matter experts provide support as needed (93; 10). Thus combining the attributes of Lean tools and techniques to eliminate waste and improve flow into the structured Six Sigma DMAIC methodology that utilizes data to remove defects that cause variation, created a robust continuous process improvement methodology called Lean Six Sigma (9).

The health care system has taken notice for the need to improve, as there is evidence that LSS has been utilized in health care to improve various clinical and administrative operations. A simple query in PubMed using “Lean Six Sigma” as a search term resulted in over 121 recent articles that contained a mix of peer reviewed original project reports, comprehensive literature reviews, and discussion papers. Similarly, a recent search on a popular online book retailer, Amazon.com, resulted in over 50 books specifically focusing on Lean and Six Sigma for health care. Additionally, a growing number of highly regarded medical institutions and affiliated universities are teaching and providing LSS as their key methodology for achieving better quality of care (94) (95). Projects using LSS in health care have reported benefits and success stories such as shortening wait times, decreasing mortality rates, reducing costs and increasing efficiency. For example, the Pittsburgh Regional Healthcare Initiative reduced central line-associated bloodstream infections (CLABSI) by more than 50%: the rate per 1,000 line days (the measure hospitals use) plummeted from 4.2 to 1.9 (96). Meanwhile, the Mayo Clinic's Rochester Transplant Center cut the cycle time from when a new patient made initial contact to setting up an appointment from 45 days to 3 days (89).

Despite such glowing successes, whether LSS itself can be a 'sustainable' methodology to reduce costs and improve health care quality and safety in a rapidly reforming health care industry is being questioned (97). A recent comprehensive literature review article went as far as to argue that LSS projects in health care have failed to show measurable improvements over time (98). In general, peer reviewed articles of original LSS projects in health care have shown a lack of evidence in sustaining improvements as many LSS project reports have only reported on outcomes close to post intervention (98). Furthermore, few articles in the literature have reported long-term impacts of LSS on health care and some have reported that organizational barriers diminished the potential for LSS to provide lasting breakthrough improvements (98). Even, a survey conducted by the management consulting firm Bain and Company reported that upwards of 80% of respondents claimed that LSS efforts are failing to drive the anticipated value (99). To get the most out of LSS methodology, therefore, it is required to identify barriers that have limited the impact of LSS projects in health care and suggest remediation steps that LSS project teams in health care should address in their projects to increase their probability of implementing sustainable change. Doing this is the primary purpose of this study.

4.3 Methods

Seven LSS experts in health care were identified and were used as key informants to conduct in-depth interviews to determine what they perceived as critical barriers to achieving lasting improvements from LSS projects. Informants were initially identified using the author's knowledge of experts in the use of LSS in health care settings. A chain sampling method was used to efficiently identify additional key informants in the field, by requesting initially identified informants to suggest other LSS experts in health care with relevant LSS project deployment knowledge. This sampling method was used until thematic saturation was accomplished. We utilized Sherry and Marlow's guide and UCLA's Center for Health Policy and Research Key Informant Interviews guide to design and conduct the interviews, analyze the responses, and report the results (100; 101).

Table 9. Key informant questionnaire

Key Informant Questionnaire
1. What is your name?
2. How many years of experience do you have in continuous process improvement?
3. How many years of experience do you have in the healthcare industry?
4. What current LSS certification level are you?
5. What type of healthcare setting do you currently conduct Lean Six Sigma projects in?
6. What do you see as the biggest challenges in conducting a LSS project in healthcare?
7. What do you think are requirements for LSS projects to be successful?
8. What do you think are key barriers to sustainability of LSS projects?
9. What are key elements to sustaining the gains?
10. If you had one wish, what wish would you have to improve the current state of LSS in healthcare?

The interview questions (*Table 9*) were developed using UCLA's key informant interview framework. The questionnaire began with the most factual and easy to answer questions first; followed by open ended questions that asked the informant's opinions and beliefs about the key aims of this study which were to determine key barriers to LSS sustainability; then ended with a question that asked for their recommendations (101). Our face to face key informant interview approach followed a semi-structured format, with the interviewer asking the key informant a set of pre-established questions on their personal and relevant experiences regarding challenges they've faced in implementing and sustaining LSS solutions in health care, and then following up with additional probing questions if needed. This approach enabled key informants to speak broadly about their personal and relevant experiences. Then when particular points were not covered in the informant's responses, or if the initial response touched on points that required more in-depth discussion, focused follow-up questions were asked. Each interview took approximately an hour to complete.

4.4 Results

Table 10 shows characteristics of the seven key informants. Informants had an average continuous process improvement experience of at least 22 years with the majority of their health care experience being in large academic tertiary hospitals and

Table 10: Key informant characteristics

Age (mean years)	52
Sex (# of Females)	5
Years of Healthcare Experience (mean years)	26
Healthcare Setting	
# from Academic Medical Center	4
# from Military Hospital	3
Years of Continuous Process Improvement Experience (mean years)	22
LSS Certification Level	
# of Master Black Belts	7

military hospitals. All the informants were formally trained in LSS and achieved the certification level of Master Black Belt. In Lean Six Sigma programs, the Master Black Belt certification level is the highest level attainable and symbolizes mastery of LSS topics and experiences in leading large-scale LSS process improvement projects (10). Key informants provided six common themes to barriers that impact sustainability of LSS improvements in health care, and are explained below. These six themes were categorized further into two main topics: *lack of leadership commitment to drive a culture of quality* and *inadequately trained and unqualified LSS practitioners to execute LSS projects in health care*.

Barriers Related to Lack of Leadership Support

There were three themes that described how the lack of leadership commitment to drive a culture of quality contributes to a breakdown in project success in sustaining the improvement gains of LSS projects.

Insufficient Leadership Commitment and Support

Informants cited lack of engaged leadership and their commitment to champion LSS as a critical failure factor that often results in projects failing to meet objectives and sustaining any positive improvements made. Informants also mentioned lack of leadership engagement and commitment as a major barrier for any transformation initiative which directly applies to LSS success. Without this element, LSS programs lack critical success factors such as continuous process improvement (CPI) governance that drives project sponsorship, continuous performance monitoring and evaluation from leadership of LSS projects, as well as investment in the people through robust training and recognition programs.

One informant shared an example where varying levels of support across different clinical departments made it difficult to carry out a system-wide patient throughput solution because the initiative lacked a uniform commitment and support from different departments. Another noted that many LSS projects at hospitals are generally led by Registered Nurses (RNs), who have great ideas but do not have leverage over physicians to make change happen. Without physician engagement in the development and implementation of interventions and their continual leadership support to execute and sustain improvements, LSS projects are less likely to be successfully adopted into clinical practice.

Lastly, informants strongly argued that health care leaders across the organization must uniformly provide support for LSS initiatives and invest resources to support improvement efforts. Informants stated that LSS program leaders presenting LSS activities at their respective organization’s senior leadership meetings regularly engaged hospital leadership on quality improvement activities, and that this was an effective platform to request program funding for LSS training and certification for hospital staff, and potential solution investments. During these senior leadership meetings, leadership also provided guidance on utilizing resources from other areas of the organization such as facilities, marketing, and information technology (IT) to support LSS project teams. Informants stated that another effective method that displayed leadership support to the organization was their leadership utilizing social media to highlight LSS process improvement successes.

Lack of a Centralized LSS Program with Project Alignment to Health Care Business Strategies

Informants noted that projects that are not aligned to the organization's health care business strategy also posed a risk to project success. For example, many "grassroots" projects developed by LSS Green and Black Belt certified practitioners are generally myopic in scope and may not focus on the organizational imperatives and critical success factors outlined by the leadership. Projects that are not aligned to current business strategies eventually lose momentum and fail to sustain the improvements, as new issues continuously arise and enterprise focus shifts to the new challenges. Scarce resources initially allocated to sustain improvements from completed projects are allocated to address new issues.

In fact, a key factor that creates siloed LSS projects is due to LSS programs not being centralized within the organization with strong leadership governance to support QI activities. Informants noted that a central issue with a decentralized LSS program is that it tends to create a "firefighting" culture that uses LSS methodology and resources to constantly "firefight" new issues; therefore it is never able to sustain improvements of past projects due to constantly focusing on new issues rather than strategically aligning LSS projects to business strategy to make lasting improvements. Additionally, a decentralized LSS program may create QI inefficiencies as many uncoordinated projects can negatively impact each other's outcomes; produce redundant efforts; and dilute improvement initiatives across the organization. This may be particularly true for complex organizational structures like in large academic medical centers (AMCs) where departments are decentralized, which oftentimes creates “one off” projects that lack buy-in from key stakeholders.

Lack of Appropriate Investments in LSS Solutions

LSS projects are generally under resourced and conducted with no funding to invest in innovative solutions. A recent survey of LSS practitioners on a popular industry website called iSixSigma.com noted that LSS Green Belts who are responsible for leading projects part time should spend between 25 to 50 percent of their time on the QI project (102). However, informants noted that project team members who usually work on LSS projects as extracurricular activities lack time to develop and implement solutions and are only afforded on average about two hours per week or 5% of their work time.

Additionally, informants noted that many projects lacked proper investments in developing and implementing high impact solutions that required significant resources. Therefore, oftentimes teams either find alternative solutions that are less impactful and not as difficult to implement that do not require significant resources or decide not to carry out solutions for tough root causes. An informant gave a recent example in which a project team recommended to purchase functionality from their pharmacy IT vendor that would automate a process to greatly reduce the number of drugs that are discarded due to prescriptions not being claimed after 14 days of being filled. It was estimated that this improvement would save over $160 thousand per year; however since the purchase of the IT system functionality would have a one-time cost of $200 thousand, it was not approved and the team resorted to a manual process that was less effective and more labor intensive. Like this example, many solutions that are implemented are quick fixes that require little monetary investments and less skill and manpower to implement. The solutions that are implemented generally are not equipped to make long-lasting changes that impact the health care systems.

Barriers Related to Inadequate LSS Skills

Three themes were identified from key informants that described how inadequately trained and unqualified LSS practitioners can contribute to their LSS projects not sustaining the improvement gains and achieving targeted expectations.

Declaring Victory Too Soon

Informants stated that teams declare victory too early and fail to properly conduct the Control phase of the project. As the last step of the LSS methodology, the Control phase is designed to identify any potential risk of failure in the improved state and develop a robust control plan that designs and implements a performance monitoring system to continuously evaluate performance and initiate change control strategies when the process is not optimally performing. For example, project teams close out projects soon after the solutions have been implemented without properly developing standard operating procedures of the improved state, developing continuous monitoring and evaluation process, error proofing the improved process, and effectively turning over the improved process to the process owner.

Informants noted examples where projects have been rushed/eager to close, even with incomplete or bad data analysis, due to new “flavor of the month” projects initiated, and/or fatigue from their projects lasting too long. “Magpie Syndrome” was a term several informants used to describe the lack of focus from the organization to follow through on current projects and instead too quick to start a new project. In fact, informants noted that closing out a project without adequate evaluation of the improved state was linked to leadership being focused on reallocating scarce LSS resources to new issues and not aligning projects to business strategy. In addition, due to the lack of QI resources to conduct operational research and execute QI tasks, LSS practitioners were often asked to even lead non-LSS standalone tasks such as data collection and analysis, standard operating procedure development, and general root cause analysis; which reduced bandwidth for LSS project teams to effectively close out their projects.

Lack of Health care Business Experience among LSS Practitioners

Informants noted that a lack of health care specific business knowledge poses a barrier to LSS project sustainability; although LSS methodology is flexible in adapting to many industries and has been successful in health care, LSS practitioners who have experience in health care are better equipped to manage the change within their environment. There are health care specific cultural nuances such as physician-nurse hierarchical interactions, health care regulations and standards, and traditional medical teaching missions that pose challenges that, if not well understood, can create barriers to successful implementation of LSS interventions. Additionally, informants stated that non-health care experienced practitioners sometimes use tools and techniques that do not resonate well with health care professionals. For example, health care places more value on clinical outcomes and how improvements impact patient experience but many LSS experts without health care experience/training might ignore this, rather focusing on financial improvement of the process as they used to do in other industries, which may not get buy-in and traction among health care practitioners.

At the same time, informants noted that LSS practitioners who have experience in health care but not in business management pose risks to sustainability as well because they tend to focus project metrics and scope primarily on improving clinical outcomes and generally do not articulate benefits in terms of health care costs and efficiency. However, these are generally what hospital leadership considers as return on investment and is willing to support.

Lack of Data Analysis and Study Design Rigor in LSS Projects

Informants stated that improvements that were not based on statistical evidence oftentimes failed to deliver lasting benefits because improvement recommendations that were not validated and which lacked data/statistical analysis rigor were easily dismissed by clinicians. Informants stated that LSS practitioners were generally not skilled in identifying and collecting appropriate performance data and additionally were not equipped to conduct necessary data/statistical analysis to determine root causes in the process or ascertain statically whether LSS project solutions improved the process. Additionally, LSS practitioners who were not versed in reporting results in biomedical journals often failed to express project results from the viewpoint of clinicians, which weakens the persuasive power to clinicians to ensure their buy-in. For example, clinicians are trained to conduct research with study design rigor in mind that will address both internal and external validity. However, LSS practitioners who are not trained in biomedical research generally conduct basic data analysis that compares only pre-post intervention results. They rarely conduct tests for statistical significance or use comparison groups. Health care professionals are used to seeing research data presented in a biomedical research framework and require statistical evidence to accept and deploy improvement recommendations regarding their processes.

4.5 Discussion

Although the LSS approach to improve health care processes has been around for some time now and many health care institutions of various sizes have utilized it to improve clinical and administrative processes, LSS practitioners have noted that a majority of these LSS projects have not been sustained and that many fail to meet intended targets (99). A survey of key informants of this study has highlighted six common themes as to the barriers that have prevented LSS projects from sustaining gains. These themes were further categorized into two main topics: *lack of leadership commitment to drive a culture of quality* and *inadequately trained and unqualified LSS practitioners to execute LSS projects in health care*. Table 11 below summarizes the barriers to LSS sustainability the informants identified and suggested recommendations to mitigate them.

Table 11: Taxonomy of barriers to sustainable LSS and potential solutions

Barriers to Sustainable LSS QI Factors Impacting LSS Project Sustainability	Potential Solutions
Lack of Leadership Commitment to drive a culture of quality	
Insufficient Leadership Commitment and Support	Develop a QI governance structure that promotes accountability and regular reporting of LSS activity to the organization leadership
Lack of a Centralized LSS Program with Project Alignment to Health care Business Strategies	Adopt management systems and structures that clearly link projects and performance with overall organizational strategies
Lack of Appropriate Investments in LSS Solutions	Create business case for intervention funding requests that is supported by sound data (i.e., if the project is to focus on reducing infections, document the costs associated with such occurrences including length of stay, supplies and added labor)
Inadequately trained and unqualified LSS practitioners to execute LSS projects in health care	
Declaring Victory Too Soon	Require all projects to go through a Control Phase gate review prior to closure to ensure that improvements have sustained and statistically validated results
Lack of Health care Business Experience among LSS Practitioners	Provide training and mentoring to LSS practioners who do not have health care business experience
Lack of Data Analysis and Study Design Rigor in LSS Projects	Invest in developing comprehensive training to include robust study design techniques and data analysis into the LSS curriculum

Key informants identified that lack of leadership support was a critical component that contributed to LSS projects not delivering on its potential to provide sustainable improvements. Such lack of leadership is inevitably causing the organization to lose tight linkages between LSS project goals and overall strategy of the health care institution. This, in turn, leads LSS projects to lose engagement from key stakeholders that are essential for project success, especially when the project is attempting to implement cross functional solutions with many process owners and sustain the gains. In addition, lack of leadership support may make LSS be perceived by the organization as just a tool to fix their “issue of the day,” an attitude that can never get the most out of LSS which is supposed to spread well controlled and streamlined processes throughout the organization in a sustainable manner. A negative side effect of this perception that LSS is a tool to fix “issues of the day” is that when the issue goes away, the LSS project team is tasked to open another project to address another hot issue and never really is able to establish and execute a long term control plan and sustain the project results. A LSS project with a shared purpose and one that is linked to a business strategy can better garner support from a diverse stakeholder group. In addition, many projects require significant resources and capital investments that can only be provided with strong leadership support. Otherwise, LSS can only provide quick fixes for rather simple problems of the organization, an under-utilization of the LSS team.

Another type of barrier is inadequate knowledge of health care operations and lack of appropriate training among LSS practitioners. As LSS was a foreign concept to health care, LSS practitioners were imported from other industries into health care settings to lead projects without prior experience in the uniqueness of the health care environment, including cultures that are steeped in tradition. Informants noted that in some cases, this has led to resistance to accept LSS solutions as not viable in the hospital setting, especially if they impacted any changes to clinical processes. Due to these issues, many health care professionals viewed LSS as a foreign concept not fit for their environment. Additionally, training within health care organizations on LSS techniques is often insufficient. In many cases, health care organizations have reduced the LSS curriculum and eliminated essential sections out of the curriculum that taught statistical analysis and project management knowledge to address concerns that the robust training took too much time out of clinicians' schedules. This pattern has a compounding negative effect on LSS programs because inadequately trained teams produce sub-par projects that end up producing solutions that do not impact the root issues of the problems. This result consequently produces a negative perception that fuels resistance to adopt

LSS interventions. An example is that few projects utilize robust design techniques using statistical data analysis and effective change management techniques to carry out process improvements (98). In this situation, LSS can never function well, albeit the hospital executives believe they have LSS in their organizations. Instead of reducing statistical sections from LSS training curricula, LSS programs need to invest more in the curriculum to adapt robust data analysis in order to be better appreciated by health care professionals.

Note that although these key informants have shared their challenges implementing improvements in health care, the barriers to sustainability are not dissimilar to challenges faced in many other industries that have deployed LSS; organizational leadership commitment and lack of management support, incorrect strategy alignment of LSS projects, and inadequately trained LSS practitioners are seen as key barriers to LSS sustainability in other industries as well (103). What is different in the health care environment from other commercial industries applying LSS is that projects conducted in hospitals put more emphasis on improving the individual experience of care, improving the health of populations, though reducing cost is also an important purpose of LSS. Corporations have a different approach; they aim their LSS efforts more on improving market leadership and profitability based on reducing defects and costs, through improving the quality of their products and services (104) (105). This difference in priority of the purposes of LSS is important to address carefully. Corporations are driven by profits and thus can manage their LSS projects that are directly tied to the company's fiscal performance and can reward LSS programs accordingly. It is more difficult to tie benefits derived from health care LSS projects to direct performance metrics such as dollars saved or increased profitability. In most cases, health care organizations adopt LSS simply as a problem solving methodology, without considering the above-mentioned differences in philosophy organizational situations, or culture between health care and other industries. As such, despite the fact that the five step DMAIC data driven approach of LSS is straightforward and easily translatable to health care, LSS methodology may not be fully functioning, as an unmatched transplanted organ does not survive in the recipient's body. Even manufacturing corporations where LSS was originated invest considerable amount of resources in training their LSS teams and adapting the LSS methodology to best fit their organizational environment. Health care settings should not be an exception, but rather invest their operating capital to build the infrastructure and resources required to effectively execute LSS as a legitimate quality improvement program. Otherwise, LSS will end up as just another management fad.

There are limitations to this study that require mention. Only LSS Master Black Belt level subject matter experts from large AMCs were interviewed. The limited number of informants only provided a narrow perspective from experts from large health care institutions who are in strategic levels in their respective organizations. Given more resources and time, it would have been beneficial to also interview seasoned LSS Black Belts who could provide information on more tactical challenges to LSS project sustainability, such as challenges with team building, project management, and change and stakeholder management (106). Additionally, as none of the informants had clinical backgrounds, the focus of their perceptions of barriers was limited to identifying administrative challenges. In future reviews, gathering information from tactical level LSS practitioners as well as perspectives of clinicians would provide a more well-rounded view. Although this study has a number of limitations, it provides a useful basis for considering how to address key barriers impacting the sustainability of LSS solutions in health care.

4.6 Conclusions

LSS is a process improvement methodology that requires commitment for all levels in the organization, especially from the leadership. It starts with leadership driving change and developing a culture of quality that is accepted by the entire organization. With leadership support and engaged staff with adequate training and tools, lasting transformation can be achieved. As the health care industry learns from past failures and gains experience, project manuscripts with rigorous methods must be continually published in peer reviewed medical journals to expand the knowledge and speed the maturity of LSS in health care.

5. Chapter 5: Dissertation Conclusions

This summary chapter begins with a review of how the thesis papers contribute to our understanding of LSS's applicability, quality of LSS evidence, and project sustainability in health care. This chapter ends with recommendations to help health systems implement an effective and sustainable QI program.

5.1 What is different about LSS in health care?

LSS, which was introduced to health care in the early 2000's, is commonly practiced in both provider and payer organizations, and it is safe to assume that this QI methodology has entered the mainstream of the health care industry. In fact, two separate studies, one conducted by the American College of Healthcare Executives and the other by the American Society for Quality, both point to the fact that 40–50 percent of healthcare organizations have employed LSS as a strategy to cut costs, increase capacity and improve quality and patient safety (102). Although LSS has been gaining popularity in health care, there are many examples of competing QI models that are in use in health care. Table 12 below provides examples of competing QI models.

Table 12: Examples of competing QI methods to LSS

QI Methodology	QI Description
Business Process Re-engineering (BPR) (107)	BPR is a management philosophy that emphasizes streamlining of cross-functional processes to significantly reduce time and/or cost, increase revenue, improve quality and service, and reduce risk
Plan-Do-Study-Act (PDSA) (108)	The PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act)
Theory of Constraints (ToC) (109)	ToC is an approach used to identify and manage bottlenecks or weight limiting steps and their associated constraints in a system
Lean Manufacturing (Lean) (110)	Lean is a principle based approach to drive out waste in a system so that all work adds value and serves the customer's needs
ISO 9000 (111)	ISO 9000 is a family of quality management systems standards that is designed to help organizations ensure they meet specific customer needs while also meeting statutory and regulatory requirements
Clinical Practice Improvement (CPI) (112)	CPI is a prescriptive five phased approach tailored for health care: Project, Diagnosis, Intervention, Impact, and Sustainment. CPI closely resembles LSS DMAIC approach and uses the same process improvement tools as LSS

What is unique about LSS in health care that is different from other QI or cost reduction programs is that LSS uses Six Sigma to decrease variation in process outcomes, while leveraging Lean to simultaneously target process efficiency, waste, and cost. Used together, they can produce a synergistic effect not only economically, but also in terms of patient and workforce satisfaction. Perhaps more importantly, LSS allows hospitals to achieve balance between the seemingly mutually exclusive goals of providing both cost-effective and high-quality care. Most QI programs are singular in focus in that they aim at improving one of the objectives of either quality or cost, but not both. Therefore, it seems as though LSS would be a good fit for health care organizations wanting to improve quality and reduce costs. However, as health care executives decide whether to invest in deploying LSS in their organizations, they will need confident and reliable evidence of its potential effectiveness and an understanding of how to achieve sustainable results.

5.2 Summary and conclusions of these thesis papers

Our systematic review of 43 LSS articles provided information on the various health care environments that LSS has been used. The diversity of the projects that have been published suggests that LSS is a versatile process improvement approach that can be used in nearly all health care environments to improve a variety of performance improvement focus areas such as quality, patient safety, efficiency, and costs. Additionally, our literature review revealed that although the majority of the projects were conducted at large academic tertiary hospitals, successful projects have been conducted at less resourced community hospitals and clinics. One area of weakness that was identified in our review was that the majority of the articles lacked statistical testing to validate the statistical significance of the improvements. Although the articles that lacked statistical validation are still valuable in providing information on applicability and effectiveness, health care professionals require sound evidence to enact change. Therefore, more high quality articles need to be published from LSS practitioners to add to the evidentiary base to support LSS use in health care.

In order to identify in what areas LSS project articles were lacking in quality, a quality assessment of the 43 LSS peer reviewed articles was conducted using a modified version of an instrument that was originally designed to evaluate the quality of clinical practice guidelines (CPGs) called AGREE verion 2. The results of the quality assessment using the modified AGREE II tool revealed that the great majority of the articles indeed lacked overall quality of execution, which makes it difficult for readers to gain confidence in their results. The quality of the articles has improved over our evaluation period, which suggests that LSS practitioners are also gaining maturity in biomedical research methods and are able to effectively translate their projects to biomedical article standards. However, the vast majority still failed to report a sound methodology, which ultimately prevents health care professionals from referencing the projects to use as evidence of effectiveness. To assist LSS practitioners to improve in future LSS project articles, deficient article quality areas were identified with suggestions on how to improve them.

A focus of the third thesis paper was on understanding key barriers that prevented LSS projects from achieving full potential and sustaining the gains. A qualitative assessment involving 7 key informants revealed that lack of leadership commitment and support, as well as inadequately trained and unqualified LSS practitioners to execute health care projects, were the primary reasons LSS failed to fulfill its objectives. These barriers to LSS project success may be ubiquitous to any new enterprise programs; however, what is unique to health care that makes these barriers even more difficult to overcome is the fact that scarce resource allocation decisions are much more difficult to make because they can ultimately impact patient safety and quality. Therefore, as with any health care program intervention, sound evidence with good study design must be published and provided to organizational leadership so that they can make difficult decisions on how to allocate valuable resources. Without strong leadership support and governance for LSS, it will not succeed in health care as countless other health care programs with strong evidence of effectiveness will vie for the same scarce resources to support their implementation.

The three thesis papers provided information on LSS and its great potential to cut costs and improve health care quality. However, my research also shed light on issues with the published evidence as well as some health care cultural and organizational barriers that prevent successful implementation of LSS in health care. Like any other enterprise change management initiative, the implementation of LSS takes a certain amount of risk and faith that this sound methodology, when supported by a committed leadership, will yield breakthrough results. Because LSS demands much of an organization, management must remain visibly supportive as staff come to learn about how it will raise the bar on performance excellence.

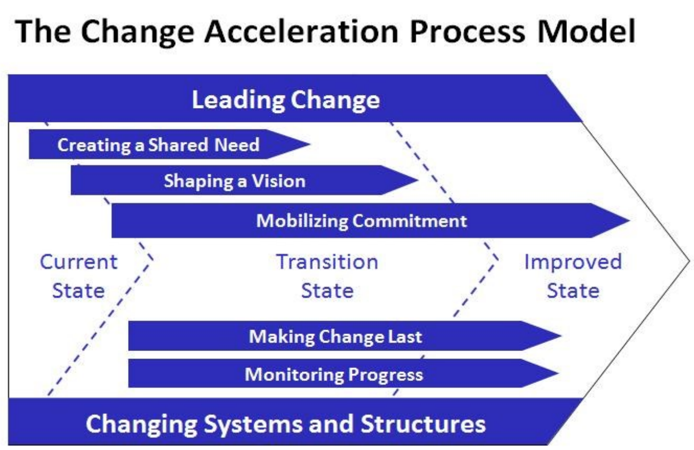
The next section of this chapter provides an enterprise change management approach General Electric (GE) used to successfully launch Six Sigma. Health care systems should consider leveraging an enterprise strategy such as this to establish a governance structure that can help establish a culture of continuous process improvement and capture and sustain the benefits of LSS.

5.3 Recommendations for a Successful LSS Deployment and Project Sustainability in Health care

A governance and change management model such as GE's Change Acceleration Process (CAP) (*Figure 4*) should be leveraged by health care organizations interested in deploying an enterprise-wide LSS program. A key component of GE's Six Sigma success was coupling the Six Sigma program with their Change Acceleration Process framework, which is based on the theory that organizational excellence can only be achieved if ***quality*** is ***accepted*** by the organization. GE developed an equation called a *Change Effectiveness Equation* (Q (quality) x A (acceptance) = E (effectiveness)) as a simple way to describe how cultural factors of an organization are required along with the technical strategy to achieve effectiveness of quality improvement efforts. In other words, paying attention to the people side of the equation is as important to success as the LSS technical approach. It is interesting to note that they used a multiplicative relationship; if there is a zero for the Acceptance factor, the total effectiveness of the initiative will be zero, regardless of the strength of the technical strategy (113). GE's CAP model can be tailored to any organization and industry. The approach is meant to be a scalable transformation framework that can be used at the LSS project level as well as at the enterprise program deployment level. The CAP model is described at a high level below.

1. Leading Change

Figure 4. GE's Change Acceleration Process model



First and foremost, authentic, committed leadership throughout the duration of the initiative is essential for success. From a project management perspective, there is a significant risk of failure if the organization perceives a lack of leadership commitment to the initiative. At the LSS deployment level, health care organizations should develop a robust quality improvement governance structure that is led by the organization's top leadership with participation from each of the major clinical departments. This group will be responsible for providing guidance to LSS practitioners on strategic alignment of projects, resources, and evaluating performance of strategic projects. Additionally, this governance structure should strategically align projects with appropriate resources to business strategy. Another core function of the LSS governance body would be to support the organization on adopting appropriate LSS tools and to monitor performance of active projects. At the project level, an engaged project sponsor should be identified for each project. This project sponsor should be someone who has the authority to assist in obtaining the right level of resources and has the ability to remove organizational roadblocks for the project team.

2. Creating A Shared Need

The felt need for change must outweigh the resistance – the inertia in the organization to maintain the status quo. At the project and enterprise program deployment level, there must be compelling reasons to change, that resonate not just for the leadership team, but that will appeal to all stakeholders (114). Therefore, a clear strategy must be developed from leadership on what the strategic priorities are for the organization and how LSS will assist in delivering improvements. At the project level, the project leader must develop a change management strategy that is tailored for each of the stakeholders identified in order to communicate the purpose for the project and address any issues each stakeholder may have. A responsibility assignment matrix tool called RACI – responsible, accountable, supportive, consulted, informed -- is a good tool to assist project teams communicate a shared purpose and to clarify roles and responsibilities in cross functional/departmental projects.

3. Shaping a Vision and Establishing a Measurement System

In order for the organization to begin accepting changes to their processes, a clear and legitimate vision of the world after the change initiative must be established. The vision of the improved state must be widely understood and shared to all stakeholders and supported by the committed leadership. The end-state of the project must be described in observable and measurable terms. Therefore, outcome measures of projects must be accepted by stakeholders and a consistent and confident measurement system established to report progress towards achieving the vision. Aside from gaining support from committed leadership, this might be the single most critical factor in a successful change initiative.

4. Mobilizing Commitment

Once leadership support is gained, a compelling logic for change and a clear vision of the future communicated, the project has the necessary ingredients to rollout the improvement initiatives. Project teams can begin to execute an influence strategy to build momentum. Identifying “early adopters,” to pilot the project where there is low resistance can yield lessons learned from a forgiving partner. Also, just in time training to stakeholders on business process improvement tools would gain added capability and commitment from stakeholders for effective execution of the project.

5. Making change last

Thus far, the preceding steps 2-4 are primarily about accelerating adoption of proposed changes. The following steps 5-7 are about making the changes permanent. Once the pilot has been performed and early wins documented, taking the knowledge gained with lessons learned and transferring the best practice to broader implementation will be the focus. A risk analysis utilizing a tool called RAID – risk, assumptions, issues, and dependencies -- should be conducted prior to full-scale implementation to identify any potential issues that may prevent successful implementation. Also, effective transition activities that include clear instructions on the new process procedures along with training the new process owners must be effectively conducted.

6. Monitoring process

Monitoring the project's performance is an important activity in the Control phase of the LSS methodology. It is important to plan for measuring the progress of LSS improvement solutions to see whether the change was real and sustained over time. The performance monitoring process should have an established set time that the improved process will be evaluated so that it is a part of the project. This will limit projects from declaring victory too early and moving onto other projects without confidently understanding whether the project is stable and consistently meeting its intended objectives. Once the project has been monitored to the set duration and is deemed a success in meeting targeted outcomes, then the results should be celebrated and published in a biomedical journal.

7. Changing Systems and Structures

In order to make change permanent, the organization must systematically identify how its operating model, including staffing, IT systems, training and development, workflow, and governance structure, influence the behavior that the LSS projects are trying to change, and modify them appropriately. If the operating model components are not evaluated and updated as necessary to support the desired future state, stakeholders resistant to change will always push back to the old way. Failure to address these systems and structures can be a key reason why so many initiatives become the proverbial “flavor of the month” without achieving lasting change.

Implementing GE's CAP model will assist health care organizations gain support and commitment from leadership while assisting the project teams with a structured way to help manage the change. In addition to leveraging the CAP model to accelerate adoption of continuous process improvement initiatives, health care organizations should develop strategic plans to train and develop LSS skills to increase the continuous process improvement capability of the organization. The training plan should identify potential LSS practitioners to train based on aptitude and ability to influence change and not on availability of the staff. The LSS curriculum must be robust enough to train practitioners on statistical analysis so that they can effectively communicate project results to the biomedical stakeholder community to gain acceptance. These strategies will help ensure that LSS initiatives achieve their highest potential for improving performance in the health care sector.

6.0 References

1. Kelley, E and Hurst, J. *Health Care Quality Indicators Project Conceptual Framework Paper.* Paris : OECD Publication Service, 2006.
2. CUSP Toolkit. *Agency for Healthcare Research and Quality.* [Online] June 2015. [Cited: September 5, 2015.] http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html.

3. TeamSTEPPS. *Agency for Healthcare Research and Quality.* [Online] [Cited: September 5, 2015.] http://teamstepps.ahrq.gov/about-2cl_3.htm.

4. ERP in Health Care Industry. *ERP Facts.* [Online] [Cited: September 5, 2015.] http://www.erpfacts.com/.

5. *Transforming Health Care: Virginia Mason Medical Center's Pursuit of the Perfect Patient Experience.* Kenney, C. New York : Productivity Press, 2010.

6. Pande, P, Neuman, R and Cavanagh, R. *The Six Sigma Way.* s.l. : The McGraw-Hill Companies, 2000. 978-07-137667-9.

7. Ohno, T. *Toyota Production System.* New York : Productivity Press, 1988. 978-0915299140.

8. Liker, J. *The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer.* New York : McGraw-Hill, 2004. 0-07-139231-9.

9. George, Michael and Robert, Lawrence. *Lean Six Sigma: Combining Six Sigma with Lean Speed.* s.l. : McGrawHill, 2002. B0044L9ENU.

10. Gygi, C, Williams, B and Covey, S. *Six Sigma for Dummies.* 2nd Edition. Hoboken : John Wiley & Sons, Inc., 2012. 978-1-118-12035-4.

11. Womack, J and Jones, D. *Lean Thinking: Banish Waste and Create Wealth in Your Corporation.* New York : Free Press, 2003. ISBN 0-7432-4927-5.

12. George, M. *Lean Six Sigma: Combining Six Sigma Quality with Lean Production.* New York : The McGraw-Hill Companies, 2202. 0-07-138521-5.

13. Morgan, J and Brenig-Jones, M. *Lean Six Sigma for Dummies.* West Sussex : Wiley, 2012. ISBN 978-1-119-95370-8.

14. Womack, James P. and Jones, Daniel T. *Lean Thinking : Banish Waste and Create Wealth in Your Corporation.* s.l. : Productivity Press, 1996. 0684810352.

15. *Lean Six Sigma in Healthcare.* Koning, H, et al. 2, s.l. : National Association for Healthcare Quality, 2006, Vol. 28.

16. *Costs and Savings of Six Sigma Programs.* Pulakanam, V. 4, Christchurch : Quality Management Journal, 2012, Vol. 19.

17. Six Sigma Costs and Savings. *iSixSigma.com.* [Online] 2015. [Cited: 10 10, 2015.] http://www.isixsigma.com/implementation/financial-analysis/six-sigma-costs-and-savings/.

18. Jusko, J. How to Choose a Black Belt Project. *Industry Week.* [Online] November 22, 2010. [Cited: 10 13, 2015.] http://www.industryweek.com/articles/how_to_choose_a_black_belt_project_23289.aspx.

19. OECD iLibrary. *Public health spending: Public social expenditure as a percentage of GDP.* [Online] OECD, Dec 20, 2013. [Cited: Sep 28, 2014.] http://www.oecd-ilibrary.org/social-issues-migration-health/public-health-spending_20743904-table4. ISSN 2074-3904.

20. Mangan, Dan. Health Care. *CNBC.Com.* [Online] CNBC, June 18, 2013. [Cited: August 29, 2014.] http://www.cnbc.com/id/100822251.

21. Rising Health Care Costs. *Inside AHIP: Center for Policy and Research.* [Online] AHIP. [Cited: August 29, 2014.] http://www.ahip.org/Issues/Rising-Health-Care-Costs.aspx.

22. Karen Davis, Cathy Schoen, and Kristof Stremikis. *Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally, 2010 Update.* New York : The Commonwealth Fund, 2010.

23. *The Quality of Health Care Delivered to Adults in the United States.* McGlynn, E, et al. 348, s.l. : The New England Journal of Medicine, 2003.

24. Wachter, Robert M. *Understanding Patient Safety.* San Francisco : McGraw Hill, 2012. 978-0-07-176578-7.

25. List of Six Sigma companies. *Wikipedia.* [Online] [Cited: March 27, 2014.] http://en.wikipedia.org/wiki/List_of_Six_Sigma_companies.

26. *Assessing the Evidence of Six Sigma and Lean in the Health Care Industry.* DelliFraine, J, Langabeer, J and Nembhard, I. 3, s.l. : Quality Management in Healthcare, 2010, Vol. 19.

27. The History of Six Sigma. *iSixSigma.* [Online] [Cited: September 16, 2014.] http://www.isixsigma.com/new-to-six-sigma/history/history-six-sigma/.

28. Institute, Lean Enterprise. A Brief History of Lean. *Lean Enterprise Institute.* [Online] 2009. [Cited: September 16, 2014.] http://www.lean.org/WhatsLean/History.cfm.

29. *Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement.* Moher, D, et al. 8, Ottawa, Canada : International Journal of Surgery, 2010. doi: 10.1016/j.ijsu.2010.02.007.

30. Higgins, J and Green, S. Cochrane Handbook for Systematic Reviews of Interventions. [Online] March 2011. [Cited: January 2, 2013.] http://handbook.cochrane.org/.

31. *Application of Six Sigma methodology to a diagnostic imaging process.* Taner, M, Sezan, B and Atwat, K. 4, s.l. : International Journal of Health Care Quality Assurance, 2011, Vol. 25.

32. *Six Sigma process utilization in reducing door-to-balloon time at a single academic tertiary care center.* Kelly, E, et al. s.l. : Progress in Cardiovascular Diseases, 2010, Vol. 53.

33. *Redesigning a Joint Replacement Program Using Lean Six Sigma in a Veterans Affairs Hospital.* Gayed, B, et al. 11, s.l. : JAMA Surgery, 2013, Vol. 148.

34. Toledo, A, Carroll, T and Arnold, E et al. Reducing liver transplant length of stay: A Lean Six Sigma Approach. *Progress in Transplantation.* 2012, Vol. 23, 4.

35. *The usefullness of lean six sigma to the development of a clinical pathway for hip fractures.* Niemeijer, G, et al. s.l. : Journal of Evaluation in Clinical Practice, 2012. 1365-2753.

36. Lin, S, et al. Use of Lean Sigma Principles in a Tertiary Care Otolaryngology Clinic to Improve Efficiency. *The Laryngoscope.* November, 2013, Vol. 123.

37. *Using Six Sigma and Lean Methodologies to Improve OR Throughput.* Fairbanks, C. 1, s.l. : AORN Journal, 2007, Vol. 86.

38. *Patient access and clinical efficiency improvement in a resident hospital-based women's medicine center clinic.* Bush, S, et al. 12, s.l. : American Journal of Managed Care, 2007, Vol. 13.

39. *Use of lean and six sigma methodology to improve operating room efficiency in a high-volume tertiary-care academic medical center.* Cima, R, et al. s.l. : American College of Surgeons, 2011. 1072-7515.

40. *How length of stay for congestive heart failure patients was reduced through six sigma methodology.* Albert, K, Sherman, B and Backus, B. 5, s.l. : American Journal of Medical Quality, 2010, Vol. 25.

41. *Applying Lean Six Sigma methodologies to improve efficiency, timeliness of care, and quality of care in an internal medicine residency clinic.* Fischman, D. 3, s.l. : Quality Management in Healthcare, 2010, Vol. 19.

42. *Improving timeliness and efficiency in the referral process for safety net providers: application of the Lean Six Sigma methodology.* Deckard, G, et al. 2, s.l. : Journal of Ambulatory Care Management, 2010, Vol. 33.

43. *Improving the medicine administration process by reducing interruptions.* Capasso, V and Johnson, M. 6, s.l. : Journal of Healthcare Management, 2012, Vol. 57.

44. *Quality initiatives: improving patient flow for a bone densitometry practice: results from a Mayo Clinic radiology quality initiative.* Aakre, K, Valley, T and O'Connor, M. s.l. : Radiographics, 2010. 10.1148/rg.302095735.

45. *Observational study using the tools of lean six sigma to improve the efficiency of the resident rounding process.* Chand, D. s.l. : Journal of Graduate Medical Education, 2011.

46. *Lean Six Sigma Sample Analysis Process in a Microbiology Laboratory.* Stoiljkovic, V, Trajkovic, J and Stoiljkovic, B. Belgrade : Journal of Medical Biochemistry, 2011, Vol. 30.

47. *The use of a co-design model in improving timely bleed reporting by adults with haemophilia living in the Auckland region of New Zealand.* D'Young, A, et al. Aukland : Haemophilia, 2013. DOI: 10.1111/hae.12336.

48. Silich, S, et al. Using six sigma methodology to reduce patient transfer times from floor to critical care beds. *Journal for Healthcare Quality.* 2011, Vol. 34, 1.

49. *Using the six sigma process to implement the Centers for Disease Control and Prevention Guideline for Hand Hygiene in 4 intensive care units.* Eldridge, Noel and Woods, Susan, Wright, Steven et. al. s.l. : Journal of General Internal Medicine, 2006.

50. *A lean Six Sigma team increases hand hygiene compliance and reduces hospital-acquired MRSA infections by 51%.* Carboneau, C, et al. 4, s.l. : Journal for Healthcare Quality, 2010, Vol. 32.

51. *Use of corporate Six Sigma performance-improvement strategies to reduce incidence of catheter-related bloodstream infections in a surgical ICU.* Frankel, H, et al. s.l. : American College of Surgeons, 2005. 1072-7515.

52. *Colorectal Surgery Surgical Site Infection Reduction Program: A National Surgical Quality Improvement Program-Driven Multidisciplinary Single-Institution Experience .* Cima, R, et al. s.l. : Elsevier , 2013. ISSN 1072-7515/12.

53. *Use of the six sigma methodology to reduce incidence of breast milk administration errors in the NICU.* Drenckpohl, D, Bowers, L and Cooper, H. 3, s.l. : Neonatal Network, 2007, Vol. 26.

54. *I've Fallen and I Can't Get Up: Reducing the Risk of Patient Falls.* Veluswamy, R and Price, R. s.l. : Physician Executive, 2010.

55. *Lean Six Sigma Reduces Medication Errors.* Esimai, G. 4, s.l. : Quality Progress, 2005, Vol. 38. 0509101027007.

56. *Using Six Sigma to reduce medication errors in a home-delivery pharmacy service.* Castle, L, Franzblau-Isaac, E and Paulsen, J. 6, s.l. : Journal on Quality and Patient Safety, 2005, Vol. 31.

57. *Six sigma tools for a patient safety-oriented, quality-checklist driven radiation medicine department.* Kapur, A and Potters, L. s.l. : Practical Radiation Oncology, 2012, Vol. 2.

58. *Using Six Sigma to improve once daily gentamicin dosing and therapeutic drug monitoring performance.* Egan, S, Murphy, P and Fennell, J, et al. s.l. : BMJ Quality Safety, Vol. 21. doi:10.1136/bmjqs-2012-000824.

59. *Use of Six sigma to improve pharmacist dispensing errors at an outpatient clinic.* Chan, A. 3, s.l. : American Journal of Medical Quality, 2004, Vol. 19.

60. *Application of Six Sigma/CAP Methodology: Controlling Blod-Product Utilization and Costs.* Neri, R, Mason, C and Demko, L. 2008, Jouranal of Healthcare Management, pp. 183-196.

61. *Formal quality improvement curriculum and DMAIC method results in interdisciplinary patients.* Leaphart, C, et al. s.l. : Journal of Surgical Research, 2012, Vol. 177.

62. *Six sigma project reduces analytical errors in an automated lab.* Riebling, N and Tria, L. s.l. : Medical Laboratory Obersver, 2005. w w w . m l o - o n l i n e . c om.

63. *Six Sigma methodology can be used to improve adherence for antibiotic prophylaxis in patients undergoing noncardiac surgery.* Parker, B, Henderson, J and Gordon, S et. al. 1, s.l. : Anesthesia and Analgesia, 2007, Vol. 104.

64. *Successful implementation of a perioperative glycemic control protocol in cardiac surgery: Barrier analysis and intervention using lean six sigma.* Martiniez, E, Chavez-Valdez, R and Lehmann, C et. al. s.l. : Anesthesiology Research and Practice, 2011.

65. *Facilitationg Process changes in Meal delivery and radiology testing to improve inpatient insulin.* Yamamoto, J, et al. 3, s.l. : Lippinocott Williams & Wilkins, 2010, Vol. 19.

66. *Improving insulin distribution and administration safety using lean six sigma methodologies.* Yamamoto, J, Abraham, D and Malatestinic, B. 3, s.l. : Hospital Pharmacy, 2010, Vol. 45.

67. *Process improvement of pap smear tracking in a women's medicine center clinic in residency training.* Calhoun, B, Goode, J, Simmons, K. 6, s.l. : Journal for Healthcare Quality, 2011, Vol. 33.

68. *Using the six sigma approach to meet quality standards for cardiac medication administration.* Elberfeld, A, Goodman, K and Kooy, M. 8, s.l. : Journal of Clinical Outcomes Management, 2004, Vol. 11.

69. *A lean six sigma quality improvement project to increase discharge paperwork completeness to a comprehensive integrated inpatient rehabilitation program.* Neufeld, N, Hoyer, E and Mayer, R et. al. s.l. : American Journal of Medical Quality, 2013.

70. *Improving patient satisfaction with pain management using six sigma tools.* DuPree, E, et al. 7, s.l. : Joint Commission on Accreditation of Healthcare Organizations, 2009, Vol. 35.

71. *Improving clinical interventions through successful outreach using Six Sigma quality improvement.* Beard, G. 1, s.l. : Journal for Healthcare Quality, 2008, Vol. 30.

72. *Improving Immunization Rates Using Lean Six Sigma Processes: Alliance of Independent Academic Medical Centers National Initiative III Project.* Hina-Syeda, H, et al. Rochester Hills : The Ochsner Journal, 2013, Vol. 13.

73. *The innovative use of Six Sigma in home care.* Elberfeld, A, et al. 1, s.l. : Home Healthcare Nurse, 2007, Vol. 25.

74. *Lean Six Sigma in health care and the challenge of implementation of Six Sigma methodologies at a Veterans Affairs Medical Center.* Pocha, C. 4, s.l. : Quality Management in Health Care, 2010, Vol. 19.

75. Protzman, C, Mayzell, G and Kerpchar, J. *Leveraging Lean in Healthcare: Transforming Your Enterprise into a High Quality Patient Care Delivery System.* New York : CRC Press, 2012. 13: 978-1-4398-1395-0.

76. *A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to deomonstrate and communicate the effectiveness of transformation strategies in healthcare.* Vest, J and Gamm, L. s.l. : BioMed Central, July 1, 2009, Implementation Science. 10.1186/1748-5908-4-35.

77. Vesely, W, et al. *Fault Tree Handbook (NUREG-0492).* Washington DD : U.S. Nuclear Regulatory Commission, 1981.

78. *Failure mode and effects analysis and fault tre analysis of surface guided cranial radiosurgery.* Manger, R, et al. 2449, La Jolla, California : American Association of Physicists in Medicine, 2015, Vol. 42. doi: 10.1118/1.4918319.

79. *Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare.* Nicolay, C, et al. s.l. : British Journal of Surgery Society Ltd., 2011, Vol. 99.

80. Ford, H and Crowther, S. *Today and Tomorrow.* Cambridge : Productivity Press, 1926.

81. Stamatis, D. *Essentials for the Improvement of Healthcare Using Lean & Six Sigma.* Boca Raton : CRC Press, 2011. 9781466500716.

82. *Guiding Inpatient Quality Improvement: A Systematic Review of Lean and Six Sigma.* Glasgow, J, Scott-Caziewell, J and Kaboli, P. 12, s.l. : The Joint Commission Journal on Quality and Patient Safety, 2010, Vol. 36.

83. *The Use of Six Sigma in Health Care Management: Are We Using It to Its Full Potential?* DelliFraine, J, et al. 3, s.l. : Quality Management in Health Care, 2013, Vol. 22.

84. *"Agency for healthcare research and quality," Fact Sheet 01-P017.* Rockville, MD, USA : AHRQ Publication, 2001. http://www.ahrq.gov/research/trip2fac.htm.

85. Introduction to AGREE II. *AGREE.* [Online] May 2009. [Cited: July 22, 2013.] http://www.agreetrust.org/.

86. *Lean Six Sigma Sampale Analysis Process in a Microbiology Laboratory.* Stoiljkovic, V, Trajkovic, J and Stoiljkovic, B. Belgrade : Journal of Medical Biochemistry, 2011, Vol. 30.

87. *Proposed standards for quality improvement research and publication: one step forward and two steps back.* Pronovost, P and Wachter, R. s.l. : BMJ, 2013.

88. Uses of Lean Six Sigma in Healthcare. *Villanova University.* [Online] [Cited: April 26, 2015.]

89. Schmidt, E. Healing Healthcare. *iSixSigma Magazine.* 2008, January/February.

90. *Going Lean in Healthcare.* Womack, J and Miller, D. Cambridge : Institute for Healthcare Improvement, 2005.

91. Plenert, G. *Reinventing Lean: Introducing Lean Management into Supply Chain.* Burlington : Elsevier, 2007. ISBN 13: 978-0-12-370517-4.

92. Jackson, T. *Implementing a Lean Management System.* Portland : Productivity Press, 1996. ISBN 1-56327-085-4.

93. Pyzdek, T and Keller, P. *Six Sigma Handbook, Fourth Edition.* s.l. : McGraw-Hill, 2014. ISBN 978-0-07-184053-8.

94. Lean Six Sigma for Healthcare Professionals - Online. *Emory University Emory Continuing Education.* [Online] [Cited: April 26, 2015.] http://ece.emory.edu/catalogDetail.php?CatalogID=413.

95. Lean and Six Sigma Training. *Armstrong Institute for Patient Safety and Quality.* [Online] [Cited: April 26, 2015.] http://www.hopkinsmedicine.org/armstrong_institute/training_services/workshops/lean_sigma_training/index.html.

96. *View from the Top: It's not about tools to achieve success in LSS. It's about how to get leaders to believe in and EBRASE quality.* Feinstein, K. New Orleans : Pittsburgh Regional Health Initiative, 2011.

97. *Successful Systems Sustaining Change.* Bullas, S and Bryant, J. 129 (Pt 2), s.l. : Studies in Health Technology and Informatics, 2007.

98. *Assessing the Evidence of Six Sigma and Lean in the Health Care Industry.* DelliFraine, J, Langabeer, J and Nembhard, I. 3, s.l. : Quality Management in Healthcare, 2010, Vol. 19.

99. Lean Six Sigma. *Bain and Company.* [Online] [Cited: April 25, 2015.] http://www.bain.com/consulting-services/performance-improvement/lean-six-sigma.aspx.

100. Sherry, S and Marlow, A. *Getting the Lay of the Land on Health: A Guide for Using Interviews to Gather Information (Key Informant Interviews).* Boston : The Access Project, 1999.

101. UCLA Center for Health Policy Research. Health Data Trainings. *UCLA Center for Health Policy Research.* [Online] [Cited: 3 15, 2015.] http://healthpolicy.ucla.edu/programs/health-data/trainings/documents/tw_cba23.pdf.

102. iSixSigma.com. 101 Things a Green Belt Should Know. *iSixSigma.com.* [Online] [Cited: June 21, 2015.] http://www.isixsigma.com/new-to-six-sigma/roles-responsibilities/101-things-green-belt-should-know/.

103. Top 10 Reasons Lean Six Sigma Projects Fail. *CBIS.* [Online] [Cited: May 4, 2015.] http://www.cbisco.com.au/top-10-reasons-lean-six-sigma-projects-fail.

104. *The Triple Aim: Care, Health, and Cost.* Berwick, D, Nolan, T and Whittington, J. 3, s.l. : Health Affairs, 2008, Vol. 27. 10.1377/hlthaff.27.3.759.

105. Butler, T. Why Six Sigma? *The Entrepreneur's Resource.* [Online] Entrepreneurship.org. [Cited: May 4, 2015.] http://www.entrepreneurship.org/resource-center/why-six-sigma.aspx.

106. Matteo, M, Perera, T and Darmanata, J. *Sustaining Lean and Six Sigma Improvements in Healthcare: Results from a pilot Survey.* Materials and Engineering Research Institute, Sheffield Hallam University. s.l. : N/A.

107. *The role of business process reengineering in health care.* Kohn, D. 3, s.l. : Topics in health information management, Vol. 14. 1065-0989.

108. Langley, G, et al. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd Edition).* San Francisco : Jossey-Bass Publishers, 2009. 978-0470192412.

109. Theory of Constraints. *Institute for Innovation and Improvement.* [Online] NHS, March 31, 2013. [Cited: 10 10, 2015.] http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/theory_of_constraints.html.

110. IHI Innovation Series white paper. *Going Lean in Health Care.* Cambridge : Institute for Healthcare Improvement, 2005.

111. ISO 9000 - Quality management. *ISO.* [Online] [Cited: 10 10, 2015.] http://www.iso.org/iso/iso_9000.

112. WHO Patient Safety Curriculum Guide. *World Health Organization.* [Online] 2015. [Cited: 10 10, 2015.] http://www.who.int/patientsafety/education/curriculum/who_mc_topic-7.pdf.

113. *The HR Scorecard; Linking People, Strategy, and Performance.* Becker, B, Huselid, M and Ulrich, D. Boston : Harvard Business School Press, 2001.

114. Senge, P. *The Fifth Discipline: The Art & Practice of the Learning Organization.* New York : DoubleDay, 2006. ISBN 0-385-51782-3.

115. *Lean and Six Sigma Methodologies in NHS Scotland: Some observations and key findings from a pilot survey.* Antony, J. s.l. : IIE Annual Conference Proceedings, 2008.

116. Porter, M. and Teisberg, E. Redefining Competition in Healthcare. *Harvard Business Review.* [Online] 2004. [Cited: July 17, 2013.] http://hbr.org/web/extras/insight-center/health-care/redefining-competition-in-health-care.

117. *Dissecting delays in trauma care using corporate lean six sigma methodology.* Parks, J, et al. 5, s.l. : The Journal of Trauma Injury, Infection, and Critical Care, 2008, Vol. 65.

118. *Colorectal Surgery Surgical Site Infection Reduction Program: A National Surgical Quality Improvement ProgrameDriven Multidisciplinary Single-Institution Experience.* Cima, A, et al. 1, s.l. : American College of Surgeons, 2013, Vol. 216.

119. *Lean Six Sigma applied to a process innovation in a Mexican Health Institute's Imaging Department.* García-Porres, J, Ortiz-Posadas, M and A, Pimentel-Aguilar. Mexico City : International IEEE EMBS Conference, 2008.

120. Kelley, E and Hurst, J. Health Care Quality Indicators Project Conceptual Framework Paper. *OECD HEALTH WORKING PAPERS NO. 23.* 2006.

121. *Organising a manuscript reporting quality improvement or patient safety research.* Holzmueller, C and Pronovost, P. s.l. : BMJ Publishing Group, 2013.

122. Lazarus, I. Six Sigma, 10 years on: Was "the promise" realized? *Becker's Hospital Review.* [Online] April 6, 2012. [Cited: September 6, 2015.] http://www.beckershospitalreview.com/hospital-management-administration/six-sigma-10-years-on-was-qthe-promiseq-realized.html.

7.0 Curriculum Vitae

A n s e l m o J . C h u n g

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SUMMARY OF QUALIFICATIONS

- Lean Six Sigma (LSS) Green Belt, Black Belt, and Master Black Belt training and certifications from fortune 100 companies
- GE Change Acceleration Process (CAP)
- Project Management Professional (PMP)
- 15 years of continuous process improvement (CPI) and business process re-engineering (BPR) experience in multiple industries which include manufacturing, energy, healthcare, and Federal government
- Expert trainer, CPI mentor, CPI program deployment leader, and Kaizen facilitator
- Enterprise operating model strategy and transformation specialist
- Quality and Risk Management
- Global cross functional experience - GE Energy International, Seoul, South Korea
- GE Technical Leadership Program, June 2002, San Jose, CA
- GE New Manager Development Course, March 2003, Singapore
- GE Intern/Coop Achievement Award winner, November 1997

EDUCATION

Johns Hopkins University, Baltimore, Maryland	DrPH, Health Policy and Management, 2015
Loyola University Chicago, Chicago, Illinois	MBA, Strategy, 2005
Arizona State University, Tempe, Arizona	BSE, Mechanical Engineering, 1999

WORK EXPERIENCE

Accenture LLP, Arlington, VA July 2015 – Present
Senior Manager, Health and Public Sector

- I recently joined Accenture's Health and Public Sector operating group, aligned to our commercial healthcare payer operating group to assist healthcare clients improve operational efficiency and quality that will improve overall customer satisfaction and bottom line results.
- I am currently leading the healthcare role transition workstream on the Defense Health Agency's (DHA) Defense Health Management System Modernization (DHMSM) electronic health record (EHR) project. In this role, I am leading a cross functional and cross-organizational team consisting of clinical and systems integration teams from our corporate partners – Cerner and Leidos, and with our DoD clients to develop effective business processes to efficiently transition roles from the legacy system to the new Cerner EHR platform.

Walter Reed National Military Medical Center, Bethesda, MD December 2014 – July 2015
Volunteer, Lean Six Sigma Project Lead/Coach

- I am currently leading a process improvement project at WRNMMC in Bethesda, Maryland to improve throughput and quality at the hospitals main pharmacy. This project is sponsored by the MTFs senior leadership and is made up of both active duty service members as well as government civilian staff. We are using the LSS methodology to gather both qualitative and quantitative data to assess the pharmacy process. We have identified root causes and have developed and implemented innovative solutions that have saved patient wait times and have improved patient experience. As the project leader, I am responsible for developing the multidiscipline team, developing project plans, gathering and analyzing data, manage project tasks, develop and implement solutions, and present briefings to the project team as well as to the MTFs Commanding Officer.

Ernst & Young, LLP (USA), MCLEAN, VA — November 2012 – June 2015
Manager, Federal Healthcare Advisory

- As a Manager in EY's Federal Health care practice, my core responsibilities include providing thought leadership around innovative clinical performance improvement, program evaluation, and healthcare strategic direction to effectively improve complex business problems for our Military Health System and the Veterans Affairs clients. Business development is another key responsibility along with building effective teams by providing leadership and continuous coaching to junior staff.
- I'm currently managing a large program evaluation and future state operating model development project for the U.S. Navy Bureau of Medicine and Surgery (BUMED) Case Management program. This project requires latitude in decision making and critical thinking to develop a new program evaluation approach to assess BUMED's case management program. For this role, I managed a staff of four and provided guidance on the overall project management approach, risk management, and client delivery quality. I led the development of the case management program evaluation methodologies, data collection and analysis approaches, key findings reports, and corrective action reports. I utilized business process improvement tools and techniques to develop case management value streams and identified potential areas for improvement in the case management life cycle. I also co-led the future state operating model strategy development in which I led a facilitated strategy visioning session with Navy Medicine leadership to develop BUMED's future state strategic roadmap for Navy Medicine's case management program.
- As the Associate Program Manager on the General Services Administration (GSA) project, I managed day to day tasks and staff on the large enterprise-wide transformation initiative to build a new business operating model that consolidated their administrative functions to reduce waste and improve efficiency and customer service. My responsibilities included leading a team of subcontractors to design the data collection approach and collect and synthesize as-is data; conducting stakeholder interviews, and requesting data calls; facilitating client visioning sessions; developing maturity models and operational baselines; developing future state operating models; developing the futures state Concept of Operations; and developing detailed future state improvement implementation plans.
- Managed the continuous process improvement workstream on the large US Army Medical Command's Transformation Program Management Office (TPMO) project. I led the development of portfolio selection criteria process and provided overall performance improvement leading practice guidance to the TPMO client in support of their large medical service transformation initiative. Also supported the development of portfolio level key performance indicators to help the TPMO leadership manage their initiatives' performance. Also served as a lead facilitator during a large operating model design workshop, assisting the client work through identifying key decision criteria to determine future operating model courses of action. Facilitated medical service design workshops

for the US Army Medical Command that produced enterprise-wide Army Medicine transformation initiative recommendations to senior leaders within Army Medicine.

- I also lead our internal Government and Public Sector practice Lean Six Sigma (LSS). In this role, I manage the development and deployment of our LSS methodology through formal Green Belt level training; managing multi-functional Green Belt projects; and providing our leadership with strategic direction advice.

PwC, LLP (USA), MCLEAN, VA July 2008 – November 2012
Senior Associate, Federal Healthcare Advisory

- As the first LSS Master Black Belt for the Washington Federal Practice of PricewaterhouseCoopers, LLP (PwC), developed the internal LSS Green Belt program which included creating the LSS Green Belt curriculum and taught over 4 waves (120 staff) of in class training; mentored 35 projects; certified 12 Green Belts; and saved over $1.5 million in internal cost savings and cost avoidance.
- Managed a team of **three staff** to deploy a new LSS program for the National Institutes of Health's Office of Logistics and Acquisitions Operations (OLAO) division. As this project was a first of its kind for the client, the client looked to our team to provide them with strategic direction to help institute a culture of quality through the LSS program. The areas of responsibility included developing the Executive Steering committee and advising them on continuous process improvement (CPI) strategies to align with the organization's business objectives; developed enterprise continuous process improvement key performance indicators (KPIs); identified strategic areas for improvements, mentored and executed over **20 CPI projects** for OLAO LSS Green and Black Belt candidates that achieved **over $4 million** dollars in savings; and advised the LSS certification board during Lean Six Sigma Belt candidate certification reviews.
- Managed the clinical continuous process improvement workstream to assist the United States Army develop and execute continuous improvement initiatives by supporting the US Army Northern Regional Medical Command's (NRMC) Director of Strategy and Innovation with LSS project mentorship. My area of responsibility included **teaching 9 US Army Medical** Command (MEDCOM) Yellow Belt training at various Army bases; facilitating balanced scorecard sessions; and program managing the development and implementation of their LSS knowledge management database. The impact of my support resulted in being awarded several contract extensions totaling over **$1 million** total.
- Managed all aspects of a client engagement for the US Army NRMC client that included project kickoffs, Work Breakdown Structure development, internal risk control, engagement financials, invoicing and billing, staff development and feedback, and task management.
- Led sales and marketing activities which included developing Lean Six Sigma marketing materials and focused White Papers related to continuous process improvement in healthcare and government, government contract Request for Information (RFI) and proposal writing, and large client networking events.

Johns Hopkins School of Medicine, Baltimore, MD January 2007 – July 2008
Senior Innovation Coach, Lean Six Sigma Master Black Belt

- Designed a focused one week Green Belt curriculum and trained over **80 hospital** administrative staff, doctors, and **nurses over 5 waves of training**.
- Worked with hospital leadership to identify LSS project areas; scoped projects, delivered just in time training, **mentored 15 clinical projects** that have saved over $**1 million**; and

advised the medical institutions and the School of Medicine on continuous improvement best practices.

- Implemented a visual cue system for work production and standardized medical forms that increased patient access. Created a standard discharge sheet for patients, making the discharge process more efficient.
- Led an intensive 5 day Kaizen consisting of a multidisciplinary team from the Emergency Department and Internal Medicine to improve throughput and reduce the Emergency Room Length of Stay metric.
- Other clinical projects that I have led were: Outpatient Pharmacy Wait Time Reduction, Cystic Fibrosis Clinic Wait Time Reduction, On-time OR First Case Start, Imaging Efficiency, and Urgent Care Wait Time Reduction.
- Introduced innovative non-healthcare best practices such as the Fault Tree diagram to identify root causes to a sentinel event and a Failure Modes and Effects Analysis (FMEA) tool to identify critical failures during emergency blood delivery to the Operating Room process. Led a complex Failure Modes and Effects Analysis (FMEA) to analyze a high risk process of implementing a new blood refrigerator in the operating suite. This involved a multi-disciplinary team of surgeons, nurses, and surgical techs to identify potential failure modes and mitigating risks of each of the process steps of using the automated blood refrigerator to store and retrieve stored packed red blood cells for high risk surgeries.

Power Great Lakes, Wood Dale, IL July 2005 – January 2007
Director of Strategic Deployment, Six Sigma Master Black Belt

- Received Six Sigma Master Black Belt training from the George Group as a part of the Caterpillar Supplier/Dealer Value Chain training program.
- Managed a staff of 4 full time Black Belts with annual Six Sigma program budget of $100K. Developed and launched an enterprise Six Sigma program which included teaching the Green Belt curriculum, mentoring projects, and certifying belts. Facilitated several Kaizens to improve cross functional communication between R&D and Sales teams to improve prototype turnaround to customer inquiry response times.
- As part of the leadership team, worked closely with the Chief Operation Officer to develop a CPI strategy to meet fiscal performance goals for each of the functional areas and identified improvement projects.
- Worked with the Sales and Marketing team to develop a Voice of the Customer program that fed customer feedback into the Sales and Marketing and Engineering teams to exceed customer expectations. Also executed a Sales Forecast Accuracy Six Sigma project that improved the team's ability to track sales pipeline and helped the Sales and Marketing Director improve resource allocation.

GE Energy, San Jose, CA & Seoul, Korea January 2000 – July 2004
Engineer, Six Sigma Green and Black Belt

- GE Nuclear Energy intern for four summers from 1996 to 1999; GE's prestigious Technical Leadership Program member from 2000 to 2002.
- As a Nuclear Reactor Modification Engineer, developed and executed complex solutions to repair commercial nuclear power plants in Fukushima and Tokai Japan and several domestic nuclear power plants.
- As a Nuclear Site Manager, served as the OEM expert at the Exelon operated Dresden Nuclear Plant in Morris Illinois. Assisted the station vice president and their senior staff

with critical power plant operations issues. Managed sales and revenue and reported out to GE Power Systems headquarter leadership during monthly sales calls.

- As a Six Sigma Black Belt, executed GE Power System's corporate quality initiatives for the Asia Region. Dotted line managed over 80 international turbine field engineers and mentored them with their Six Sigma projects. Assisted the Regional Sales Managers with customer focused projects to improve communication of innovative products to the customers.
- Executed over **30** global Six Sigma projects and saved **over $7 million** dollars.

INTERESTS AND ACTIVITIES

- High Reliability Organizing health systems
- ASCEND Pan-American Leadership member
- Professional counselling volunteer to underserved high school students
- Veterans Service Organization (Code of Support) campaign/initiative volunteer
- American Society for Quality active member
- Project Management Institute active member